

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Denver Federal Center, 6 <sup>th</sup> Avenue and Kipling Street Post Office Box 25087; Denver, Colorado 80225-0087 Phone: (303) 236-3000; Fax: (303) 236-3100	DATE(S) OF INSPECTION 4/14-17/03
	FEI NUMBER 3003672313

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Robert Y. Jones; Vice President of Engineering & Production**

FIRM NAME Cavitat Medical Technologies, Inc.	STREET ADDRESS 10691 East Bethany Drive, Suite 900
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CITY, STATE AND ZIP CODE Aurora, Colorado 80014	TYPE OF ESTABLISHMENT INSPECTED Sponsor of Medical Device Investigational Study
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THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

These observations are associated with two (2) medical device investigational studies entitled "Through-transmission sonography (TTS) - new technology for detection of low density of the jaws: Comparison with radiology for osteoporotic alveolar sites with histopathologic confirmation" and "Through-transmission sonography (TTS) - new technology for the evaluation of jawbone density and desiccation: Correlation with histopathology of scanned alveolar sites."

**ITEM 1:**

Failure to ensure IRB review and approval of the investigational protocols and informed consent were obtained.

**ITEM 2:**

Failure to establish an investigational plan associated with the two (2) studies (for detection of low density of the jaws and for the evaluation of jawbone density and desiccation) to include the items as follows: purpose; protocol; risk analysis; description of the device; monitoring procedures; labeling; consent materials; and IRB information.

**ITEM 3:**

Failure to select investigators qualified by training and experience to investigate the device.

**ITEM 4:**

Failure to control the investigational devices in that there is no documentation to support that investigational devices were provided to only qualified investigators participating in the study. Additionally, there is no documentation to support when these investigational devices were provided to the investigator and when these devices were returned to the sponsor.

**ITEM 5:**

Failure to obtain a signed investigator agreement from each participating investigator to include the information as follow: investigator's curriculum vitae; statement of investigator's relevant experience (including dates, location, extent, and type of experience); a statement of the investigator's commitment to conduct the investigation in accordance with the agreement (including the investigational plan; conditions of approval imposed by the reviewing IRB; supervise all testing of the device involving human subjects; and ensure that the requirements for obtaining informed consent are met).

**ITEM 6:**

Failure to monitor the two (2) investigational studies.

**ITEM 7:**

Failure to select monitors qualified by training and experience to monitor the investigational studies.

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MAY 5 2003

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Lori A. Medina</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Lori A. Medina, investigator	DATE ISSUED 4/17/03
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**PURGED**

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Aurora, Colorado 80014

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Lori A. Medina, CSO (DEN-DO)  
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**SUMMARY**

This initial, directed (for cause) inspection of a Sponsor was conducted in accordance with CP 7348.810, "Sponsors, Contract Research Organizations and Monitors", associated with the detection at low density of the jaws and the evaluation of jawbone density and dessication. Additionally, this inspection was conducted as a paper assignment dated 3/18/03 and FACTS assignment dated 4/22/03 issued by CDRH BIMO (HFZ-311). The inspection is associated with 510(k) number K011147, and FACTS assignment number 400807/operational identification number 1359882.

This inspection focused on two (2) medical device investigational studies entitled "Through-transmission sonography (TTS) - new technology for detection at low density of the jaws: Comparison with radiology for 92 osteoporotic alveolar sites with histopathologic confirmation" and "Through-transmission sonography (TTS) - new technology for the evaluation of jawbone density and dessication: Correlation with histopathology of 285 scanned alveolar sites." The Sponsor (Cavitat Medical Technologies, Inc.) has never had an FDA approved IDE for these device studies.

Cavitat Medical Technologies, Inc. (Cavitat) is located at 10691 East Bethany Drive, Suite 900, Aurora, Colorado 80014; [phone: (303) 755-2688/fax: (303) 755-2699] and sponsored the study. The study did not have IRB approval (of the protocol or informed consent) and was not monitored. The Principal Investigator was identified as Jerry E. Bouquot, D.D.S, located at The Maxillofacial Center, 165 Scott Avenue, Suite 100, Morgantown, West Virginia 26508-8802. (b)(4)

A total of (b)(4) osteoporotic alveolar sites (involved within the first study) and a total of (b)(4) scanned alveolar sites (involved within the second study) were included within the Sponsor's data submission for 501(k) approval consideration. Mr. Jones, Jr. indicated that several alveolar sites may have been included from one study subject. Mr. Jones, Jr. was unsure as to the total number of study subjects screened and accepted to the study by Dr. Bouquot.

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During this inspection, no in depth data review of any of the study subjects (0%) was conducted as there was no data to be reviewed at the sponsor. In summation, the sponsor did not have any records associated with the study (relatable to sponsor deficiencies) as follows: failure to obtain an IDE; no IRB review and approval of the study protocol or informed consent; no investigational plan; no monitoring procedures or documentation of study monitoring; no documentation of the selections of qualified investigators (principal and sub); no device accountability logs; no documentation of serious/non-serious adverse events or complaints; and no investigator agreement(s).

An FDA-483, Inspectional Observations, was issued to the facility at the inspectional closeout on 4/17/03 with the items being associated with the Sponsor's failure to follow 21 CFR Part 812 associated with Sponsor regulations.

Management was uncooperative during the entire duration of this inspection and refusals to allow inspection were encountered during the early phase of this inspection. After a discussion with the firm's attorney, the firm agreed to allow inspection; however, obtaining information from the firm was very difficult and a hostile environment was present throughout the entire duration of this inspection. Additionally, Mr. Jones, Sr. stated that he contacted two Congressmen on 4/15/03 regarding this inspection. Therefore, two FDA Investigators were present for the inspectional close-out on 4/17/03 in order to bear witness to the events of this meeting.

All FDA correspondence (including post inspectional) should be directed to Robert J. Jones, Sr., located at Cavitat Medical Technologies, Inc., 10691 East Bethany Drive, Suite 900, Aurora, Colorado 80014.

#### **PERSONS INTERVIEWED**

On 4/14/03, credentials were shown to and an FDA-482, Notice of Inspection, was issued to Robert Y. Jones, Vice President of Engineering and Production. A second FDA-482, Notice of Inspection, (signed by FDA Investigators Medina and Smith) dated 4/17/03 was issued to Robert Y. Jones, Vice President of Engineering and Production, prior to the inspectional close-out and issuance of the FDA-483, Inspectional Observations. Robert Y. Jones is referred to within this report as Mr. Jones, Jr. as he is the son of the President/CEO Robert J. Jones (referred to within this report as Mr. Jones, Sr.)

**PURGED**

This inspection was unannounced (the firm was not aware that I was to begin my BIMO inspection on Monday morning, 4/13/03) and therefore, Mr. Jones, Jr. stated that he was the most responsible individual present at the firm at the initiation of the inspection and in the absence of his father, Robert J. Jones. Later in the morning of 4/14/03 (around 10:30), Mr. Jones, Sr. introduced himself and credentials were shown to him at this time. The nature of this inspection was also explained to Mr. Jones, Sr. Mr. Jones, Sr. authorized Mr. Jones, Jr. and Sarah J. Jones (Mr. Jones, Sr.'s wife) to be present throughout this inspection on an as needed basis.

Mr. Jones, Jr. stated that he has the knowledge, ability, and authority to provide regulatory agencies with requested information and he has been delegated FDA contact during inspections (in the absence of Mr. Jones, Sr.). Mr. Jones, Sr. sporadically participated within this inspection. The FDA-483, Inspectional Observations, dated 4/17/03 was issued to Robert Y. Jones, Vice President of Engineering and Production, as Mr. Jones, Sr. was unavailable.

Mr. Jones, Jr. and Mr. Jones, Sr. collectively provided all of the information contained within this report. They provided information associated with the items as follows: background information associated with firm correspondence (via attorneys) associated with device approval submissions to FDA; firm/FDA meetings; study literature articles; example of Informed Consent (not IRB approved); as well as all other information contained within this report.

Mr. Jones, Sr. provided the Curriculum Vitae for Jerry E. Bouquot, D.D.S., who was identified as a Principal Investigator. Mr. Jones, Jr. stated that Dr. Bouquot had study responsibilities to conduct subject assessment for inclusion into the study, the continuous monitoring of the subjects throughout the study, and the reporting thereof to the Sponsor company (Cavitat). Additionally, Mr. Jones, Jr. stated that the firm considers Dr. Bouquot to be the Sponsor as Dr. Bouquot drafted the study protocols. I stated that without the firm's device (Cavitat Ultrasonograph), Dr. Bouquot would not have had a device which to utilize during the clinical study/studies. Therefore, Cavitat is considered to be the Sponsor of the study in that the medical device was manufactured by and provided to Dr. Bouquot by Cavitat.

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Additionally, the device was shipped by the firm within Interstate Commerce (from Colorado to the study sites outside of Colorado) prior to 510(k) approval by FDA. However, the firm did not record the locations to which these study devices were shipped and is unable to produce shipping records associated with the movement of these unapproved medical devices (prior to the 2/15/02 510(k) approval). See FDA-483 item number 4 and the Objectionable Conditions section of this report.

All FDA correspondence (including post inspectional) should be directed to Robert J. Jones, Sr., located at Cavitat Medical Technologies, Inc., 10691 East Bethany Drive, Suite 900, Aurora, Colorado 80014.

#### **AUTHORITY AND ADMINISTRATION**

Mr. Jones, Jr. stated that the Sponsor (considered to be Dr. Bouquot by Mr. Jones, Jr.) explained the status of the study, nature of the protocol, and the obligations of the Sub-Investigators to Cavitat after the devices were provided to the Sub-Investigators for inclusion into the clinical study. The authority for the conduct of the various aspects of the study was delegated to the Sub-Investigators by Dr. Bouquot (the Sponsor/Principal Investigator), according to Mr. Jones, Jr.

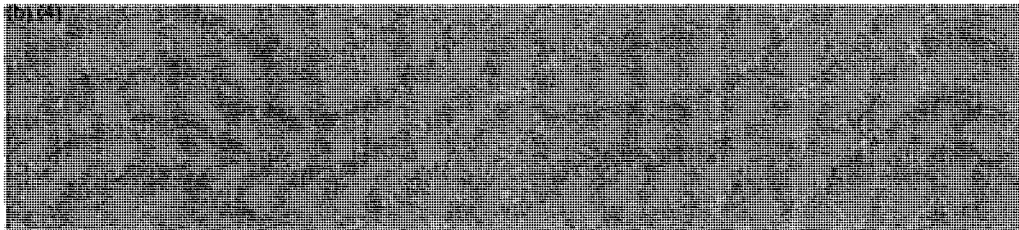
Mr. Jones, Jr. stated that Dr. Bouquot's staff retained control and knowledge of the study and not Cavitat. This was apparent as Cavitat did not have study subject case report forms (and no Informed Consents) available for review during this inspection. Dr. Bouquot, according to Mr. Jones, Jr., is continuing his study of the device at the time of this inspection.

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**STUDY STAFF**

The staff for the two (2) medical device investigational studies entitled "Through-transmission sonography (TTS) - new technology for detection at low density of the jaws: Comparison with radiology for (b) (4) osteoporotic alveolar sites with histopathologic confirmation" and "Through-transmission sonography (TTS) - new technology for the evaluation of jawbone density and desiccation: Correlation with histopathology of (b) (4) scanned alveolar sites" entailed Jerry E. Bouquot, D.D.S. as the Principal Investigator. Mr. Jones, Jr. was unable to determine the individuals which have been identified as Sub-Investigators by Dr. Bouquot. Mr. Jones, Jr. stated that the Sub-Investigators would include study subjects within the study and send radiographs, Cavitat scans, clinical information, and bone biopsies (if applicable) to Dr. Bouquot for evaluation (including Pathology).

Dr. Bouquot Curriculum Vitae as was provided during this inspection is found as Exhibit 1A. This information was provided by Sarah J. Jones, Executive Vice President of Administration, was printed off of the internet (site <http://www.maxillofacialcenter.com/CV.html>), and is dated 11/4/02. Exhibit 1B is a document entitled "Maxillofacial Osteonecrosis (NICO) - Dr. Bouquot's published work".



Mr. Jones, Jr. was stated he was not sure if the above three individuals (b) (4) were considered to be Sub-Investigators associated with the two studies. A brief background on Dr. Bouquot (b) (4) (b) (4) is found as Exhibit 1C (provided by Mrs. Jones).

No FDA-1572, STATEMENT OF INVESTIGATOR, was collected and no Investigator Agreement(s) were collected during this inspection as there were none available at this site.

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The research facility where the subject's Cavitat scan, radiography, clinical evaluation, and/or bone biopsy was evaluated was (b) (4)

(b) (4)

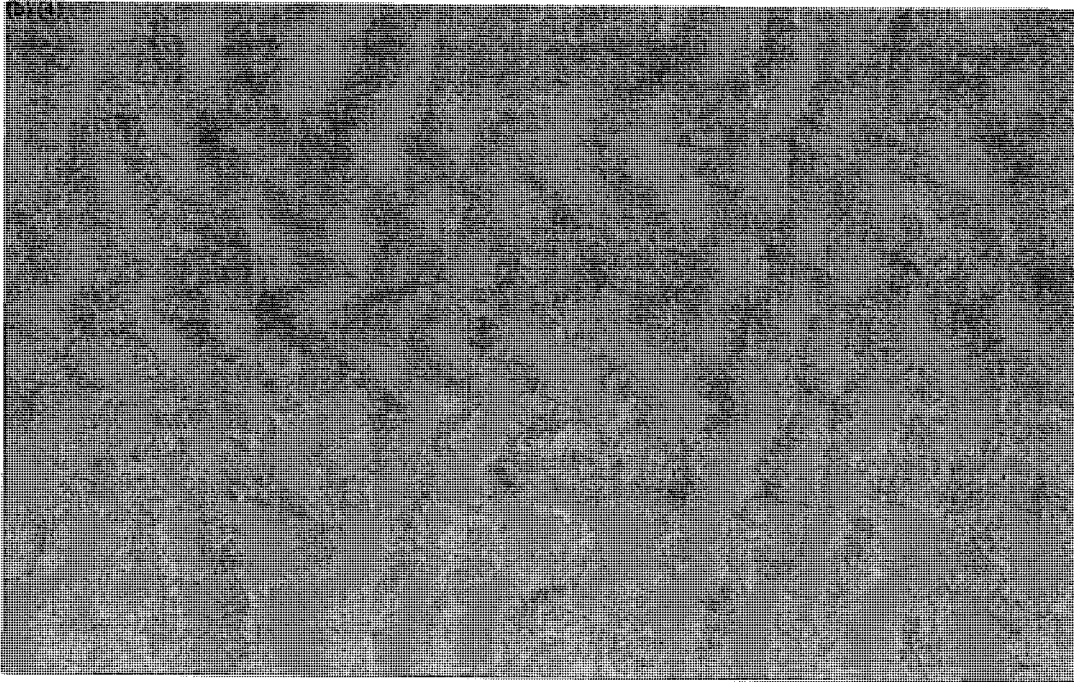
(b) (4)

Mr. Jones, Jr. stated that he does not know if an Institutional Review Board (IRB) was utilized in any manner associated with the conduction of this clinical study. If an IRB was utilized, Mr. Jones stated that he does not know the name of the IRB that was responsible for review and approval of the study protocol and/or informed consent. Additionally, he does not know if Dr. Bouquet obtained IRB approval prior to admitting subjects into the study. (b) (4)

(b) (4)

#### **STUDY SUMMARY/LITERATURE**

Study summaries (articles) were provided during the course of this inspection by Mr. Jones, Jr. in association with the clinical studies which were the subject of this inspection. The study summaries are as follows:

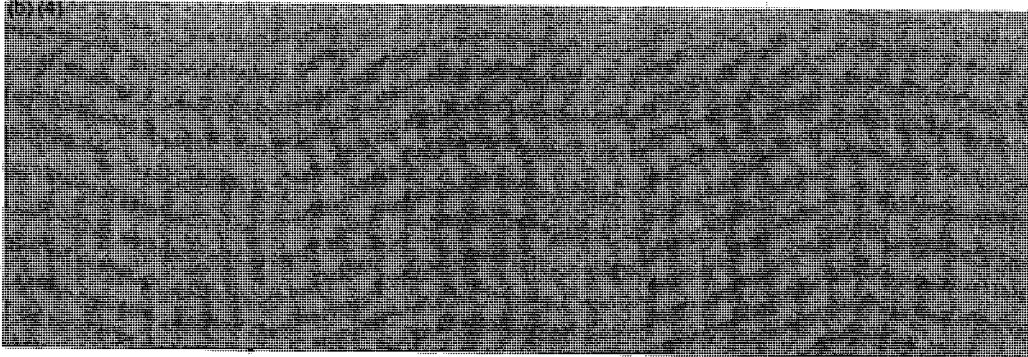


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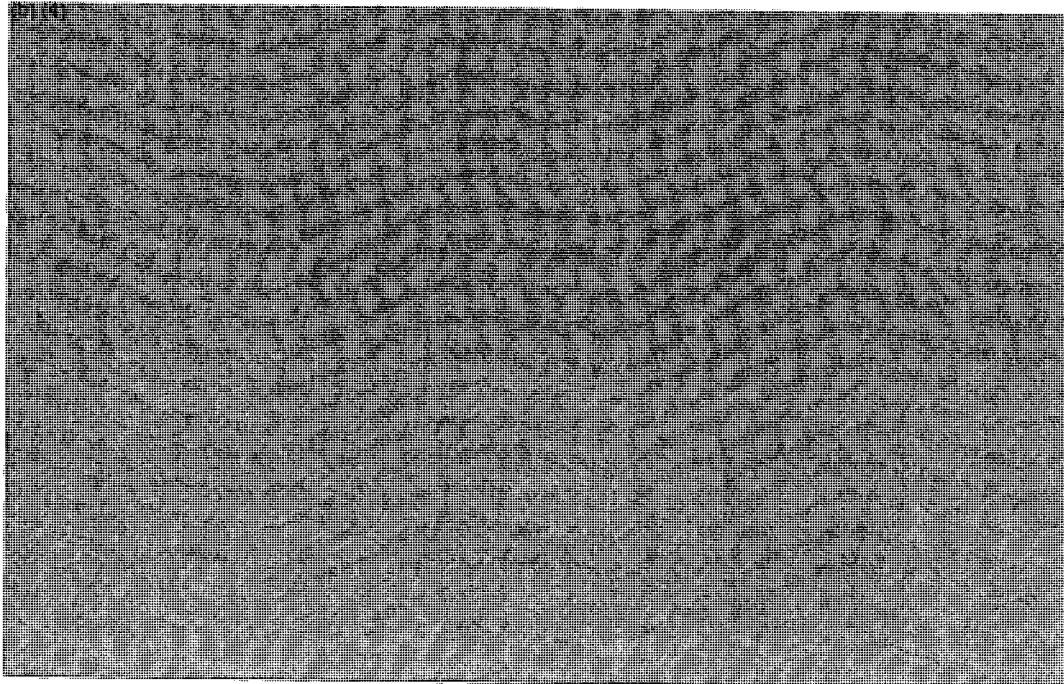
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Mr. Jones, Jr. indicated that Exhibits 2A-2C were the "most recent" drafts of the research literature as was presented to the firm by Dr. Bouquot which, in turn, the firm utilized to support the 510(k) application as presented to FDA.

During the course of this inspection, Mr. Jones, Jr. contacted Dr. Bouquot in order to obtain additional information associated with the two studies which were the focus of this inspection. Exhibit 3 is a letter dated 4/12/03 from Dr. Bouquot to Mr. Jones, Sr. at Cavitat which was faxed during the course of this inspection. A summary of these issues discussed within this letter are as follows:



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### **REFUSALS**

Management was uncooperative during the entire duration of this inspection and refusals to allow inspection were encountered during the early phase of this inspection. After my discussion with the FDA Denver District Office Management and the firm's attorney, the firm agreed to allow the inspection; however, obtaining information from the firm was very difficult and a hostile environment was present throughout the entire duration of this inspection.

On 4/15/03, I left the firm voluntarily around 11:00 a.m. because Mr. Jones, Sr., was speaking aggressively towards me about feeling as though FDA was "picking on him..." even though he spent "lots of money securing 510(k) approval". My leaving the firm early was conveyed to FDA Denver District Office management.

Additionally, Mr. Jones, Sr. stated that he contacted two Congressmen (Dan Burton of Indiana and John Rowe, Chief of Staff/Mercury and Environment/Committee on oversight of FDA) on 4/16/03 regarding this inspection. Therefore, two FDA Investigators were present for the inspectional close-out on 4/17/03 in order to bear witness to the events of this meeting.

### **COMPUTER ELECTRONIC DATA SYSTEMS**

No electronic data systems were used in the creating, modifying, maintaining, archiving, retrieving, or transmitting of data from the clinical site.

### **PROTOCOL**

The original protocols for the two (2) medical device investigational studies entitled "Through-transmission sonography (TTS) - new technology for detection at low density of the jaws: Comparison with radiology for 92 osteoporotic alveolar sites with histopathologic confirmation" and "Through-transmission sonography (TTS) - new technology for the evaluation of jawbone density and desiccation: Correlation with histopathology of scanned alveolar sites" do not have IRB approval of protocol and informed consent. See FDA-483 item number 1 and the Objectionable Conditions section of this report. Mr. Jones, Jr. stated that he is not sure if changes were made to the investigational protocol or informed consent during the execution of this clinical study. This was the responsibility of Dr. Bouquot according to Mr. Jones, Jr.

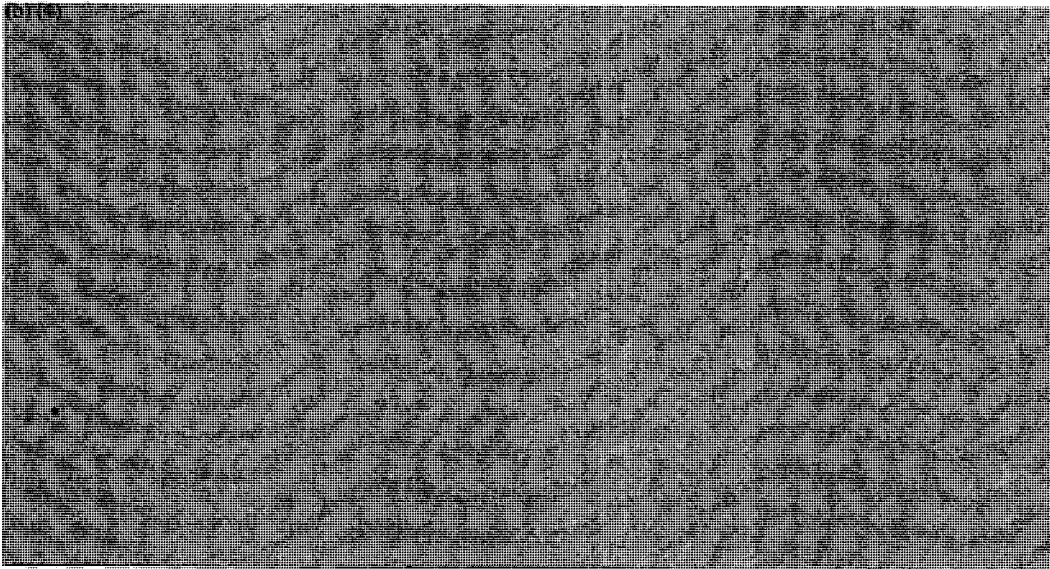
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Study summaries were provided during the course of this inspection by Mr. Jones, Jr. in association with the clinical studies which were the subject of this inspection. The study summaries are as follows:



The study was designed to provide clinical data for the Cavitat Medical Technologies Inc. Ultrasonograph associated with the detection of low density of the jaws and the evaluation of jawbone density and dessication. The Sponsor (Cavitat) has never had an FDA approved IDE for these device studies.

Mr. Jones, Jr. stated that he did not know what the inclusion/exclusion criteria was in association with admitting/rejecting subjects for the study. No documentation stating the inclusion/exclusion criteria was observed during this inspection.

#### **INSTITUTIONAL REVIEW BOARD (IRB)**

Mr. Jones, Jr. stated that he does not know if an Institutional Review Board (IRB) was utilized in any manner associated with the conduction of this clinical study. If an IRB was utilized, Mr. Jones stated that he does not know the name of the IRB that was responsible for review and approval of the study protocol and/or informed consent. Additionally, he does not know if Dr. Bouquot obtained IRB approval prior to admitting subjects into the study. (b) (4)

(b) (4)

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**CONSENT TO PARTICIPATE/INFORMED CONSENTS (IC)**

Mr. Jones, Jr. provided documentation as an example of Informed Consent which was provided to the Sub-Investigators when the device was shipped from Cavitat to the Investigator(s). Exhibit 4 is a document entitled "PATIENT CONSENT FORM" which was provided to Investigators and could be changed by the Investigator for their own use. Mr. Jones, Jr. stated that this informed consent form has not received IRB approval associated with clinical studies and Mr. Jones, Jr. stated that he is not sure if Dr. Bouquot utilized this informed consent form; changed this form; or obtained IRB approval of this (or any other) informed consent prior to admitting subjects into the clinical study.

Since Case Report Forms were not available at the Sponsor, no review was conducted during the course of this inspection in association with IC form review.

(b) (4)

**ADVERSE EVENTS**

Mr. Jones, Jr. stated that he is not sure if Dr. Bouquot experienced any adverse events (AEs) or study deviations during the course of the clinical study. Mr. Jones, Jr. stated that he does not know if Dr. Bouquot submitted any information associated with any adverse events to any IRB.

(b) (4)

**RECRUITMENT**

(b) (4)

Mr. Jones, Jr. is not sure if Dr. Bouquot (or any of the unknown Sub-Investigators) utilized advertising media (newspaper, television, or radio) to gain study subject inclusion as part of the conduct of the clinical study in addition to Dr. Bouquot's (and the other Sub-Investigator's) normal practice of medicine.

(b) (4)

**PURGED**

### **STUDY SUBJECTS**

A total of (b) (4) osteoporotic alveolar sites (involved within the first study) and a total of (b) (4) scanned alveolar sites (involved within the second study) were included within the Sponsor's data submission for 501(k) approval consideration. Mr. Jones, Jr. indicated that several alveolar sites may have been included from one study subject. Mr. Jones, Jr. was unsure as to the total number of study subjects screened and accepted to the study by Dr. Bouquot (and the other unknown Sub-Investigators). (b) (4)

### **SPONSOR AND MONITORING**

Cavitat did not monitor or evaluate the two studies mentioned in this report. The sponsor did not have any records associated with documentation as follows: study sponsor monitoring procedures; schedule of monitoring visits; or documentation of study monitoring (i.e. no log of on-site monitoring visits).

Mr. Jones, Jr. stated that the firm considers Dr. Bouquot to be the Sponsor as Dr. Bouquot drafted the study protocols. I stated that without the firm's device (Cavitat Ultrasonograph), Dr. Bouquot would not have had a device which to utilize during the clinical study. Therefore, Cavitat is considered to be the Sponsor of the study in that the medical device was manufactured by and provided to Dr. Bouquot by Cavitat.

### **DEVICE ACCOUNTABILITY**

Mr. Jones, Jr. stated that the firm does not have a device accountability log and that Cavitat (the Sponsor) has not maintained a record to account for the location to which the investigational devices were shipped prior to 510(k) approval (2/15/02) for clinical evaluation. Mr. Jones, Jr. stated that he recalls that the firm shipped approximately (b) (4) devices for investigational use prior to 510(k) approval; however, no documentation exists to evidence this.

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Mr. Jones, Jr. stated that several items (in addition to the actual Cavitat Ultrasonograph device) were provided to the Sub-Investigators for use in conducting clinical research (Exhibits 4, 5A, 5B). A listing of these promotional/instructional items are as follows:

EXHIBIT	MATERIAL
4	A document entitled "PATIENT CONSENT FORM" which was provided to Investigators and could be changed by the Investigator for their own use.
5A	Actual device labeling for investigational use.
5B	Generation 3 instructions for use/user manual for use during the investigational studies.
5C	General device promotional material. This sites the 510(k) number [K011147] thus was not provided with the investigational devices. Mr. Jones, Jr. stated that this information is provided with devices which are currently shipped from the firm. The promotional material describes the device as it exists during the time of this inspection.

**SUBJECT CHARGES FOR INVOLVMENT WITHIN STUDY**

Mr. Jones, Jr. stated that he does not know if study subjects were charged for the use of the investigational device and associated clinical tests associated with the use of the investigational device.

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Mr. Jones, Jr. stated that he does not know if an Institutional Review Board (IRB) was utilized in any manner associated with the conduction of this clinical study. If an IRB was utilized, Mr. Jones stated that he does not know the name of the IRB that was responsible for review and approval of the study protocol and/or informed consent. Additionally, he does not know if Dr. Bouquot obtained IRB approval prior to admitting subjects into the study. (b) (4)

### **OTHER STUDIES IN WHICH CAVITAT IS INVOLVED**

Mr. Jones, Jr. stated that Dr. Bouquot's research study associated with the Cavitat Ultrasonograph is continuing. This is the only other clinical study that Mr. Jones, Jr. is aware that the firm is participating in. (b) (4)

### **ASSIGNMENT SPECIFIC INSTRUCTIONS**

This inspection was associated with a clinical study involving the detection at low density of the jaws and the evaluation of jawbone density and dessication and was conducted as a paper assignment dated 3/18/03 and FACTS assignment dated 4/22/03 issued by CDRH BIMO (HFZ-311). The inspection is associated with 510(k) number K011147, and FACTS assignment number 400807/operational identification number 1359882.

The two (2) medical device investigational studies listed within the assignment are as follows:

- *Through-transmission sonography (TTS) - new technology for detection at low density of the jaws: Comparison with radiology for (b) (4) osteoporotic alveolar sites with histopathologic confirmation.*
- *Through-transmission sonography (TTS) - new technology for the evaluation of jawbone density and dessication: Correlation with histopathology of (b) (4) scanned alveolar sites.*

This initial, directed (for cause) inspection of a Sponsor was conducted in accordance with CP 7348.810, "Sponsors, Contract Research Organizations and Monitors", the above mentioned CDRH assignment. The assignment referenced "SPECIFIC INSTRUCTIONS" which are listed below (in bold-face type) and the information obtained during this inspection is found directly below the assignment specific instructions.

**PURGED**

**"Please confirm that all patients signed an informed consent."**

See the section of this report entitled "CONSENT TO PARTICIPATE/INFORMED CONSENTS (IC)" found on Page 11.

**"Please investigate if patients were charged for the device and associated tests."**

See the section of this report entitled "SUBJECT CHARGES FOR INVOLVMENT WITHIN STUDY" found on Page 13.

**ADDITIONAL INFORMATION PROVIDED BY THE FIRM**

Mr. Jones, Sr. provided additional background information associated with the firm's dealing with FDA. This information was provided in association with the firm's 510(k) approval activities and a summary is as follows:

EXHIBIT	MATERIAL
6A	Letter dated 9/19/01 from McKenna & Cuneo (Attorneys at Law), Washington, D.C. to FDA Dental Services Branch, Rockville, Maryland regarding the " <i>De Novo</i> Classification of the CAVITAT Ultrasound Bone Densitometer (K011147)."
6B	Letter dated 8/2/01 from McKenna & Cuneo (Attorneys at Law), Washington, D.C. to FDA Division of Reproductive, Abdominal, and Radiological Devices (ODE), Rockville, Maryland regarding "Meeting with CAVITAT Medical Technologies, Inc. August 09, 2001, 10:00 a.m."
6C	Letter dated 3/22/01 from CAVITAT Medical Technologies, Inc., Aurora, Colorado to Dr. Jerry Bouquot, Morgantown, West Virginia regarding items which are to "...assist you (Dr. Bouquot) with the IRB/IDE for CAVITAT..."

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6D	Photocopies of FDA/CDRH website information provided by Mr. Jones, Jr. dated 4/9/03 which highlights parts of 21 CFR Part 812 which, according to Mr. Jones, Jr., exempts the firm from being a Sponsor and not requiring an IDE. The highlighted areas include parts of 21 CFR Part 812 as follows: <ul style="list-style-type: none"><li>• Page 1 - 812.1(a);</li><li>• Page 3 - 812.2(a);</li><li>• Page 4 - 812.2(2)(c) and 812.2(2)(c)(3)(i) through 812.2(2)(c)(3)(iv);</li><li>• Page 6 - 812.3(b)(1) through 812.3(b)(5);</li><li>• Page 7 - 812.3(h), 812.3(i), 812.3(k), and 812.3(l);</li><li>• Page 8 - 812.3(o) and 812.3(p);</li><li>• Page 10 - 812.5(a)</li></ul>
6E	510(k) letter dated 2/15/02 for K011147 associated with the device entitled "Cavitat (Ultrasonograph), CAV 40000-1 and CAV 40000-3 with WIN/CAV Software (Release 1.05); Regulation Number 872.1800; Regulation Name of Extraoral Source X-Ray System; Class II."
6F	Letter dated 10/10/02 from CAVITAT Medical Technologies, Inc., Aurora, Colorado (Mr. Jones, Sr.) to Cavitat Owners regarding "FDA/MERCURY AMALGAM RULING". This letter referenced "...(FDA) making a tactical error moving mercury amalgam to Class III trying to circumnavigate the rules of approvals by moving a grandfathered, non classified material into Class III and planning to use the rationale that 100 years of use makes it safe to move it to Class II where it can be used and marketed as safe..." Additionally, the letter states "...amalgam will remain in Class III and can only be used in a University sponsored Investigational Review Board study or in life threatening situations. As of 5:00 p.m. yesterday any dentist placing amalgam is breaking the law and is outside the STANDARD OF CARE!!!...".
6G	FDA ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT for 2004 in which the firm is registered as a medical device manufacturing facility.

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Cavitat Medical Technologies Inc. (Sponsor)  
10691 East Bethany Drive, Suite 900  
Aurora, Colorado 80014

4/14-17/03  
Lori A. Medina, CSO (DEN-DO)  
CFN/FEI 3003672013

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**OBJECTIONABLE CONDITIONS / DISCUSSION WITH MANAGEMENT**

An FDA-483, Inspectional Observations, was issued to Robert Y. Jones, Vice President of Engineering and Production, during the inspectional close-out on 4/17/03. Mr. Jones, Jr. was the only firm individual that was present for the Inspectional close-out. Mr. Jones, Jr. stated that Mr. Jones, Sr. and Mrs. Jones were unavailable and authorized Mr. Jones, Jr. to participate within the FDA inspectional close-out. FDA Investigators Medina and Elvin R. Smith were also present.

Mr. Jones, Jr. stated that Dr. Bouquot had study responsibilities to conduct subject assessment for inclusion into the study, the continuous monitoring of the subjects throughout the study, and the reporting thereof to the Sponsor company of Cavitat. Additionally, Mr. Jones, Jr. stated that the firm considers Dr. Bouquot to be the Sponsor as Dr. Bouquot drafted the study protocols and that the firm is NOT considered to be the Sponsor of these studies. I stated that without the firm's device (Cavitat Ultrasonograph), Dr. Bouquot would not have had a device which to utilize during the clinical study. Therefore, Cavitat is considered to be the Sponsor of the study in that the medical device was manufactured by and provided to Dr. Bouquot by Cavitat.

The meeting included a discussion associated with the topics as follows: Protocols; Informed Consent; IRB approvals (of study protocols and informed consents); Sponsor Monitoring; Investigator Agreements; Case Report Form documentation; device accountability; and IDE issues. The 21 CFR Part 812 deficiencies (as found on the FDA-483) are bold-face typed and found within quotation marks below. A discussion of each item is found immediately following the observation. The firm's response (for all seven items) is found following the observations.

**"These observations are associated with two (2) medical device investigational studies entitled 'Through-transmission sonography (TTS) - new technology for detection at low density of the jaws: Comparison with radiology for (b) (4) osteoporotic alveolar sites with histopathologic confirmation' and 'Through-transmission sonography (TTS) - new technology for the evaluation of jawbone density and dessication: Correlation with histopathology of (b) (4) scanned alveolar sites.'"**

PURGED

**ITEM 1**

812.42  
**"Failure to ensure IRB review and approval of the investigational protocols and informed consent were obtained."**

Mr. Jones, Jr. stated that he does not know if an Institutional Review Board (IRB) was utilized in any manner associated with the conduction of this clinical study. If an IRB was utilized, Mr. Jones stated that he does not know the name of the IRB that was responsible for review and approval of the study protocol and/or informed consent. Additionally, he does not know if Dr. Bouquot obtained IRB approval prior to admitting subjects into the study. This information will need to be obtained during an inspection of Dr. Bouquot.

**ITEM 2**

**"Failure to establish an investigational plan associated with the two (2) studies (for detection of low density of the jaws and for the evaluation of jawbone density and dessication) to include the items as follows: purpose; protocol; risk analysis; description of the device; monitoring procedures; labeling; consent materials; and IRB information."**

Mr. Jones, Jr. stated that the firm did not establish an investigational plan associated with the two (2) studies (for detection of low density of the jaws and for the evaluation of jawbone density and dessication). Since Mr. Jones, Jr. did not consider his firm to be the Sponsor of the study, the firm did not establish a study purpose or protocol, as this was to be conducted by Dr. Bouquot (b) (4). The IRB approval (for the protocol and the informed consent) was also, according to Mr. Jones, Jr., to be secured by Dr. Bouquot.

Additionally, the firm did not perform risk analysis upon the study or the medical device and did not establish monitoring procedures or schedule of visits.

Mr. Jones, Jr. stated that the firm does not have a device accountability log and that Cavitat (the Sponsor) has not maintained a record to account for the location to which the investigational devices were shipped prior to 510(k) approval (2/15/02) for clinical evaluation. Mr. Jones, Jr. stated that several items (in addition to the actual Cavitat Ultrasonograph device) were provided to the Sub-Investigators for use in conducting clinical research. A listing of these promotional/instructional items are as follows:

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EXHIBIT	MATERIAL
4	A document entitled "PATIENT CONSENT FORM" which was provided to Investigators and could be changed by the Investigator for their own use (general form letter).
5A	Actual device labeling for investigational use.
5B	Generation 3 instructions for use/user manual for use during the investigational studies.

**ITEM 3**

**"Failure to select investigators qualified by training and experience to investigate the device."**

See the section of this report entitled "STUDY STAFF" found on Page 6.

The staff for the two (2) medical device investigational studies, which were the subject of this inspection, entailed Jerry E. Bouquot, D.D.S as the Principal Investigator. Mr. Jones, Jr. was unable to determine the individuals which have been identified as Sub-Investigators by Dr. Bouquot. Mr. Jones, Jr. stated that the Sub-Investigators would (b) (4)

(b) (4)  
(b) (4) Mr. Jones, Jr. stated that the firm has not evaluated the Sub-Investigators participating within the study for qualification and clinical experience.

Dr. Bouquot Curriculum Vitae as was provided during this inspection is found as Exhibit 1A. This information was provided by Sarah J. Jones, Executive Vice President of Administration, (b) (4)

(b) (4) dated 11/4/02, which is after the 510(k) approval dated 2/15/02. Exhibit 1B is a document entitled "Maxillofacial Osteonecrosis (NICO) – Dr. Bouquot's published work".

There are a total of four individuals listed on the two published studies (the subject of this inspection) as follows:

\* Jerry E. Bouquot, D.D.S., M.S.D

(b) (4)

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Mr. Jones, Jr. was stated he was not sure if the above three individuals (b) (4) were considered to be Sub-Investigators associated with the two studies. A brief background on Dr. Bouquot, (b) (4)

(b) (4)

**ITEM 4**

**"Failure to control the investigational devices in that there is no documentation to support that investigational devices were provided to only qualified investigators participating in the study. Additionally, there is no documentation to support when these investigational devices were provided to the investigator and when these devices were returned to the sponsor."**

Mr. Jones, Jr. stated that the firm does not have a device accountability log and that Cavitat (the Sponsor) has not maintained a record to account for the location to which the investigational devices were shipped prior to 510(k) approval (2/15/02) for clinical evaluation. Mr. Jones, Jr. stated that he recalls that the firm shipped approximately (b) (4) devices for investigational use prior to 510(k) approval; however, no documentation exists to evidence this.

**ITEM 5**

**"Failure to obtain a signed investigator agreement from each participating investigator to include the information as follows: investigator's curriculum vitae; statement of investigator's relevant experience (including dates, location, extent, and type of experience); a statement of the investigator's commitment to conduct the investigation in accordance with the agreement (including the investigational plan; conditions of approval imposed by the reviewing IRS; supervise all testing of the device involving human subjects; and ensure that the requirements of obtaining informed consent are met)."**

No FDA-1572, STATEMENT OF INVESTIGATOR, was collected and no Investigator Agreement(s) were collected during this inspection as there were none available at this site. Mr. Jones, Jr. stated that he was not aware of the Sponsor regulation associated with Investigator Agreements. No Investigator Agreements, according to Mr. Jones, Jr., exist for the two studies which were the subject of this inspection.

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**ITEM 6**

**"Failure to monitor the two (2) investigational studies."**

**ITEM 7**

**"Failure to select monitors qualified by training and experience to monitor the investigational studies."**

See the section of this report entitled "SPONSOR AND MONITORING" found on Page 12 for additional information associated with Item numbers 6 and 7.

Cavitat did not monitor or evaluate the two studies mentioned in this report. The sponsor did not have any records associated with documentation as follows: study sponsor monitoring procedures; schedule of monitoring visits; or documentation of study monitoring (i.e. no log of on-site monitoring visits).

Mr. Jones, Jr. stated that he was not aware of the Sponsor regulation associated with conducting monitoring activities associated with clinical studies. No monitoring procedures or monitoring activities took place associated with the two studies which were the subject of this inspection, according to Mr. Jones, Jr.

**FIRM'S RESPONSE TO ITEMS 1-7**

Robert Y. Jones, Vice President of Engineering and Production, stated that the above mentioned seven FDA-483 items were an oversight in that the firm does not consider themselves to be a Sponsor of medical device investigational studies. Several sections of 21 CFR Part 812 were discussed with Mr. Jones, Jr. as follows: 812.3(g); 812.3(h); 812.3(n); 812.2(c); 812.2(c)(3); 812.2(b)(1)(i) through (vii); 812.5; and 812.46.

Mr. Jones, Jr. stated that, in the future, his firm will ensure that all portions of 21 CFR Part 812 will be met in association with all applicable regulations concerning (but not limited to) the parties and issues as follows: Sponsor/Manufacturing facility; Clinical Investigators (principal and sub); IRB protocol and informed consent approval; patient protection; IDE issues; etc.

**PURGED**

### **RECORDS RETENTION**

Mr. Jones, Jr. stated that Dr. Bouquot should maintain custody of the required records (case report forms, informed consents, etc.) and the means by which prompt access can be assured. Additional study record retention information or specifics will need to be obtained during an inspection of Dr. Bouquot.

### **ATTACHMENTS**

- Attachment 1: Paper assignment dated 3/18/03 and FACTS assignment dated 4/22/03 issued by CDRH BIMO (HFZ-311). The inspection is associated with 510(k) number K011147, and FACTS assignment number 400807/operational identification number 1359882.
- Attachment 2: FDA-482, Notice of Inspection, (signed by Investigator Medina) dated 4/14/03 issued to Robert Y. Jones, Vice President of Engineering and Production
- Attachment 3: FDA-482, Notice of Inspection, (signed by Investigators Medina and Smith) dated 4/17/03 issued to Robert Y. Jones, Vice President of Engineering and Production
- Attachment 4: FDA-483, Inspectional Observations, dated 4/17/03 issued to Robert Y. Jones, Vice President of Engineering and Production

### **EXHIBITS**

- Exhibit 1A: Dr. Bouquot Curriculum Vitae as was provided during this inspection (information provided by Sarah J. Jones, Executive Vice President of Administration, (b) (4)

(b) (4)

(b) (4)

- Exhibit 1B: A document entitled "Maxillofacial Osteonecrosis (NICO) – Dr. Bouquot's published work".

- Exhibit 1C: A brief background on Dr. Bouquot, (b) (4)

(b) (4)

**PURGED**

Exhibit 2A:

Exhibit 2B:

Exhibit 2C:

Exhibit 2D:

Exhibit 3:

A letter dated 4/12/03 from Dr. Bouquot to Mr. Jones, Sr. at Cavitat which was faxed during the course of this inspection.

Exhibit 4:

A document entitled "PATIENT CONSENT FORM" which was provided to Investigators and could be changed by the Investigator for their own use.

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- Exhibit 5A: Actual device labeling for investigational use.
- Exhibit 5B: Generation 3 instructions for use/user manual for use during the investigational studies.
- Exhibit 5C: General device promotional material. This sites the 510(k) number [K011147] thus was not provided with the investigational devices. Mr. Jones, Jr. stated that this information is provided with devices which are currently shipped from the firm. The promotional material describes the device as it exists during the time of this inspection.
- Exhibit 6A: Letter dated 9/19/01 from McKenna & Cuneo (Attorneys at Law), Washington, D.C. to FDA Dental Services Branch, Rockville, Maryland regarding the "De Novo Classification of the CAVITAT Ultrasound Bone Densitometer (K011147)".
- Exhibit 6B: Letter dated 8/2/01 from McKenna & Cuneo (Attorneys at Law), Washington, D.C. to FDA Division of Reproductive, Abdominal, and Radiological Devices (ODE), Rockville, Maryland regarding "Meeting with CAVITAT Medical Technologies, Inc. August 09, 2001, 10:00 a.m."
- Exhibit 6C: Letter dated 3/22/01 from CAVITAT Medical Technologies, Inc., Aurora, Colorado to Dr. Jerry Bouquot, Morgantown, West Virginia regarding items which are to "...assist you (Dr. Bouquot) with the IRB/IDE for CAVITAT..."
- Exhibit 6D: Photocopies of FDA/CDRH website information provided by Mr. Jones, Jr. dated 4/9/03 which highlights parts of 21 CFR Part 812 which, according to Mr. Jones, Jr., exempts the firm from being a Sponsor and not requiring an IDE. The highlighted areas include parts of 21 CFR Part 812 as follows:
- Page 1 - 812.1(a);
  - Page 3 - 812.2(a);
  - Page 4 - 812.2(2)(c) and 812.2(2)(c)(3)(i) through 812.2(2)(c)(3)(iv);
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  - Page 7 - 812.3(h), 812.3(i), 812.3(k), and 812.3(l);
  - Page 8 - 812.3(o) and 812.3(p);
  - Page 10 - 812.5(a)

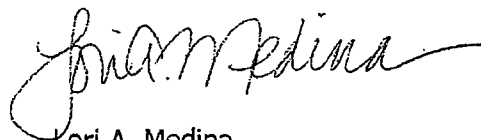
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- Exhibit 6E: 510(k) letter dated 2/15/02 for K011147 associated with the device entitled "Cavitat (Ultrasonograph), CAV 40000-1 and CAV 40000-3 with WIN/CAV Software (Release 1.05); Regulation Number 872.1800; Regulation Name of Extraoral Source X-Ray System; Class II.
- Exhibit 6F: Letter dated 10/10/02 from CAVITAT Medical Technologies, Inc., Aurora, Colorado (Mr. Jones, Sr.) to Cavitat Owners regarding "FDA/MERCURY AMALGAM RULING". This letter referenced "...(FDA) making a tactical error moving mercury amalgam to Class III trying to circumnavigate the rules of approvals by moving a grandfathered, non classified material into Class III and planning to use the rationale that 100 years of use makes it safe to move it to Class II where it can be used and marketed as safe..." Additionally, the letter states "...amalgam will remain in Class III and can only be used in a University sponsored Investigational Review Board study or in life threatening situations. As of 5:00 p.m. yesterday any dentist placing amalgam is breaking the law and is outside the STANDARD OF CARE!!!...".
- Exhibit 6G: FDA ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT for 2004 in which the firm is registered as a medical device manufacturing facility.



Lori A. Medina  
Investigator  
DEN-DO

PURGED