



Department of Health and Human Services

Public Health Service  
Food and Drug  
Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
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June 8, 2010

**WARNING LETTER  
CIN-10-113710-11**

**VIA UPS**

Giuseppe Vercellotti  
Chief Operating Officer  
Piezosurgery, Inc.  
750 Communication Parkway  
Columbus, Ohio 43214

Dear Mr. Vercellotti:

During an inspection of your firm on March 25 through April 12, 2010, an investigator from the United States Food and Drug Administration ("FDA") determined that your firm is the initial importer and distributor, complaint handling and servicing unit for electrical surgical dental devices. Under section 201(h) of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h), these product are devices because they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that the medical devices are adulterated within the meaning of section 501 (h) of the Act, 21 U.S.C. § 351(h), in that the methods. used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to, the following:

1. Failure to maintain complete complaint files and complete complaint handling procedures, as required by 21 C.F.R. § 820.198(a).

Specifically, your firm is not always documenting enough information from the complainant so that an evaluation can be performed to determine if complaints are valid. Additionally, your "P001 Complaint Reception" procedure, dated 07/11/05 does not ensure that enough information is recorded from the complainant so that an initial review and evaluation of the complaint can be performed. For example, RMA 606698's "Description of the Event" section states "Handpiece and Cord - 402JA233: Passed all tests - Returned (Not Under Warranty-402JA233)". There is no description of the problem that the customer had with the device.

2. Failure to fully investigate complaints involving the possible failure of a device, labeling or packaging to meet any of its specifications, as required by 21 CFR§ 820.198(c).

Specifically, if a device fails outside the one-year warranty period, the error code is recorded but the device is not returned to the manufacturer to be investigated.

3. Failure to establish complaint handling procedures that ensure that complaints are evaluated to determine whether the complaint represents an event which must be reported to FDA under part 21 CFR§ 803, as required by 21 CFR§ 820.198(a)(3).

Specifically, your "P001 Complaint Reception" procedure fails to describe the information that must be obtained from the complainant to determine if an event is reportable under part 21 CFR§ 803 as a malfunction Medical Device Report.

4. Failure to document employee training, as required by 21 CFR§ 820.25(b).

Specifically, your "PO15 Employee Training" procedure requires that all employees receive training to perform their assigned tasks, be trained on the FDA regulations and standards, and this training be recorded on training form TF01106. Employee training is not being documented.

Our inspection also revealed that your devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2) in that your written MDR procedures ("P001 Complaint Reception") do not include an internal system which provides for a timely and effective identification of events that may be subject to medical device reporting requirements, and a standardized review process or procedure for determining when an event meets the criteria for reporting, as required by 21 CFR§ 803.17(a).

For example, your firm received a complaint on March 17, 2010 that the OT4 tip broke during a surgery to correct a pilot osteotomy axis leaving the tip wedged into the base of the osteotomy, near the sinus floor. "The tip had to be removed from the buccal approach. The patient was not able to receive the implant at this site." Your firm closed this complaint on March 22, 2010 and did not document your decision for not reporting this event to the FDA as a serious injury. During the closeout of the inspection, your firm stated that they would be reporting this event to FDA within the

required 30 day time period. Please provide a copy of this report with your response to this letter.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in the initiation of regulatory action without further notice. This may include, but is not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. If your planned corrective actions will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions about this letter, you may contact Ms. Brackett at (513) 679-2700, ext. 167, or you may forward a facsimile to her at (513) 679-2773.

Finally, you should know that this letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by the FDA. The specific violations noted in this letter and in the FDA 483s may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt action to correct the violations and to bring your products into compliance.

Sincerely,

/S/

Teresa C. Thompson  
District Director  
Cincinnati District