



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9 2694d

November 14, 2002

Ref: 2003-DAL-WL-06

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

## WARNING LETTER

### **CERTIFIED MAIL** **RETURNED RECEIPT REQUESTED**

Mr. Ted R. Davis  
President and Chief Executive Officer  
SOUNTEC, Inc.  
2601 Northwest Expressway, Suite 400W  
Oklahoma City, Oklahoma 73112

Dear Mr. Davis:

During an inspection of your facility located in Oklahoma City, Oklahoma, on September 9 -17, 2002, our investigator determined that your firm manufactures and commercially distributes the SOUNDTEC® Direct System, a partially implantable hearing device that is indicated for use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss. The SOUNDTEC® Direct System includes a variety of accessories, such as the Magnetic Stabilizing Suture and the Magnetic Retrieval Tool. These products are medical devices as defined in 21 U. S. C. § 321 (h) of the Federal Food, Drug, and Cosmetic Act (the Act).

At the conclusion of the inspection, our investigator issued a list of Inspectional Observations (Form FDA-483 – copy enclosed) to Mr. Stephen D. Ford, Chief Operating Officer, listing significant deviations from Current Good Manufacturing Practices (CGMPs). Your devices are adulterated within the meaning of 21 U. S. C. § 351 (h) of the Act in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with CGMP requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. Significant CGMP deviations include, but are not limited to, the following:

1. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 C.F.R. § 820.30(a). For example, your firm failed to apply design controls for the manufacturing of the Magnetic Stabilizing Suture and to evaluate the effects of resterilization on the device by users. The original suture labeling by the original equipment manufacturer states "Do Not Resterilize" [FDA-483 Item 1].

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2. Failure to implement and record changes in methods and procedures needed to correct and prevent identified quality problems as required by 21 C.F.R. § 820.100(a)(5). For example, your firm received several customer complaints reporting that the magnet portion of the magnetic retrieval tool had corroded, broken off, and lost magnetism. Your firm had determined the root cause but failed to implement a planned corrective action to resolve these quality complaints [FDA-483 Item 2].
3. Failure to document the corrective and preventive action [CAPA] activities as required by 21 C.F.R. § 820.100(b). For example, your firm stated to our investigator that as part of the root cause analysis, your firm had conducted several validation studies which showed oxidation of the magnetic retrieval tool after ██████████ sterilization cycles. However, your firm failed to maintain records of the analysis of the validation test results.
4. Failure to establish and maintain complaint handling procedures to include a determination of whether a device was being used for treatment or diagnosis as required by 21 C.F.R. § 820.198 (d) (2). For example, although your customer complaint reports documented the above-referenced quality problems with the magnetic retrieval tools, the complaint reports did not contain information or records of investigation to determine whether or not the magnetic retrieval tools involved were used during device implantation.
5. Failure to establish and maintain device distribution records for control and distribution of finished devices as required by 21 C.F.R. § 820.160(b) (1) (2) (3) and (4). Your firm refused to provide distribution records of finished devices to our investigator in order for him to verify and document information concerning shipment in interstate commerce of your finished devices including: (1) The name and address of the initial consignee; (2) The identification and quantity of devices shipped; (3) The date shipped; and (4) Any control number(s) used. Because of your firm's refusal, we consider that your firm's distribution records have not been maintained.

Please be aware that the Act at 21 U. S. C. § 360 i Section 519 requires device manufacturers to establish and maintain device records and reports to ensure compliance with the CGMP requirements of the Quality System regulation as promulgated pursuant to 21 U. S. C. § 360 j (f) (1) (A). Your firm's refusal to permit access to or verification or copying of any device distribution records, as required by 21 U. S. C. § 360 i, is prohibited by law under 21 U. S. C. § 331 (e).

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This letter is not intended to be an inclusive list of all the deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close of your inspection may be symptomatic of more serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA).

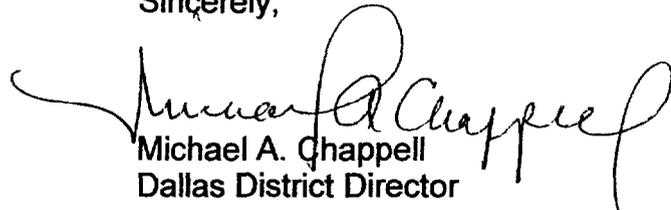
Federal agencies are advised of the issuance of all warning letters involving devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken or will take to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be directed to Thao Ta, Compliance Officer, at the above listed address.

Sincerely,



Michael A. Chappell  
Dallas District Director

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