



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

Telephone (973) 526-6008

February 4, 2002

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

File # 02-NWJ-17

Mr. Janis Ziedonis  
CEO  
Medical Accessories, Inc.  
92 Youngs Rd.  
Trenton, NJ 08619

Dear Mr. Ziedonis,

During an inspection of your firm located at 92 Youngs Road, Trenton, NJ on December 27, 2001 and January 2 and 9, 2002, an investigator from the Food and Drug Administration (FDA) determined that you are a manufacturer of Sterile Fetal Scalp Electrodes. Sterile Fetal Scalp Electrodes are considered to be class II medical devices within the meaning of section 201(h) of the Federal Food Drug and Cosmetic Act (the Act).

Our inspection determined that your firm is not in compliance with the Quality System Regulations (QSR) as required by Title 21 Code of Federal Regulations Part 820 concerning medical devices, which renders them adulterated within the meaning of section 501(h) of the Act as follows:

1. Failure to establish and maintain procedures for implementing corrective and preventive actions that include requirements for analyzing sources of quality data to identify existing and potential quality problems as required by 21 CFR 820.100.
2. Failure to establish Medical Device Reporting (MDR) procedures as required by 21 CFR 820.198(a).
3. Failure to have documented validation of the package sealing process as well as the resterilization process as required by 21 CFR 820.75.
4. Failure to calibrate the thermal sealer time and temperature settings as required by 21 CFR 820.72.
5. Failure to include the primary identification label and labeling used for each production unit in the device history record as required by 21 CFR 820.184 (e).

We have received and reviewed your firm's responses to the Inspectional Observations (Form FDA 483). The responses were found to be inadequate. The response to FDA-483 Item #1 addresses problems found by the production operators, but does not address other sources of quality data such as quality audit reports, quality records, service records, complaints, and returned product. The response to FDA-483 item #2 includes a device master record for fetal scalp electrodes and does not address the observation of lack of a medical device reporting (MDR) procedure. The response to FDA-483 item #3 does not include data to show that a process validation of the pouch sealing process was performed. The response to FDA-483 item #4 states that the correction has already been implemented but did not include supporting documentation. Your response has been made part of the New Jersey District file.

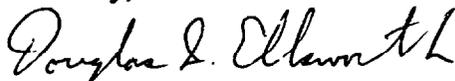
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and on the Form FDA483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems within your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective and preventive actions.

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, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved 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 the deviations identified above. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. Your response should be directed to the New Jersey District, FDA, 10 Waterview Blvd., 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054, Attn: Frank Marciniak, Acting Compliance Officer.

Sincerely,



Douglas I. Ellsworth  
District Director  
New Jersey District