



June 3, 2004

Chicago District  
550 West Jackson Blvd., 15th Floor  
Chicago, Illinois 60661  
Telephone: 312-353-5863

**WARNING LETTER**  
**CHI-13-04**

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

Ms. Jean K. Wagner, President  
Keller Medical Specialties Products, Inc.  
42609 North Crawford Road  
Antioch, IL 60002-7282

Dear Ms. Wagner:

During inspection of your firm, located at 42609 North Crawford Road, Antioch, IL, from November 24 to November 26, 2003, United States Food and Drug Administration (FDA) Investigator James W. Plucinski determined that your firm manufactures blood pressure monitors, pulse oximeters, and cardiac monitors. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Management with executive responsibility failed to ensure that the quality policy was understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20.
2. Your firm failed to establish and maintain process control procedures that describe process controls necessary to ensure conformance to specifications as required by 21 CFR 820.70(a). For example, your firm does not have specifications or parameters specified in the test procedure for the KMS-890+ Blood Pressure / Pulse Oximeter Simulation Check.
3. Your firm failed to establish quality audit procedures and conduct such quality audits that assure your quality system is in compliance with the established quality system requirements as required by 21 CFR 820.22. For example, your firm's quality audits failed to detect that your firm allowed [REDACTED] KMS-890+ Vital Signs Monitors to ship after finished device test results showed they did not conform to blood pressure tolerance specifications.
4. Your firm failed to establish and maintain procedures for implementing and documenting corrective and preventive action as required by 21 CFR 820.100.

5. Your firm failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to ensure that complaints are documented and investigated as required by 21 CFR 820.198. For example, your firm did not document the investigation of complaints that involve devices that customers return for repair. Also, your firm failed to establish a procedure to ensure that complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under 21 CFR Part 803 or 804, Medical Device Reporting.
6. Your firm's Device Master Record fails to include or refer to the location of device specifications as required by 21 CFR 820.181(a).

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 in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You should promptly initiate permanent corrective and preventive action on your Quality System.

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. No premarket submissions for Class III devices, to which the QSR deficiencies are reasonably related, will be cleared or approved until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected and verified.

You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action being initiated by 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 violations, including (1) the time frames within which the corrections will be completed; (2) any documentation indicating that the corrections have been achieved; and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

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Your response should be sent to Michael Lang, Compliance Officer, Food and Drug Administration, at 550 West Jackson Blvd., 15<sup>th</sup> Floor, Chicago, IL, 60661-5716. If you have any questions regarding this letter, please contact Mr. Lang at (312) 596-4225.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott MacIntire". The signature is written in a cursive style with a large initial 'S'.

Scott MacIntire  
District Director