



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
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June 20, 2002

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**  
CIN-WL-02-12978

John F. Kevern, President and CEO  
Biological and Environmental Control Laboratories, Inc.  
705 Front Street  
Toledo, Ohio 43605

Dear Mr. Kevern:

Our review of information collected during an inspection of your firm located in Toledo, Ohio, on February 25 through March 5, 2002, revealed that your firm reprocesses limb sleeve compression garments that are intended for single use only. These limb sleeve compression garments are manufactured and distributed by your firm for [REDACTED]. These products are devices as defined in Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The law requires that manufacturers of medical devices obtain marketing clearance or approval for their products from the Food and Drug Administration (FDA) before they can distribute them commercially. See 21 CFR § 807.81(a) (2). This helps protect the public health by ensuring that newly introduced medical devices are safe and effective for their intended uses. Because you have not submitted a 510(k), your reprocessed, single-use limb sleeve compression garments are misbranded under Section 502(o) of the Act. Until such time as you submit a 510(k) and obtain FDA clearance, your reprocessed, single-use limb sleeve compression garments are also adulterated under Section 501(f)(1)(B) of the Act, in that it is a Class III device under Section 513(f) and does not have an approved application for premarket approval (PMA) in effect pursuant to Section 515(a), or an approved application for investigational device exemption (IDE) under Section 520(g).

In addition, your firm's reprocessed, single use limb sleeve compression garments are misbranded within the meaning of Section 502(f)(1) of the Act because the labels for the devices you reprocess for [REDACTED] cannot be written for this device for use by laymen and it is not exempt from the requirements of section 502(f)(1) under Title 21 of the Code of Federal Regulations, Section 801.109 (21 CFR § 801.109) because its label does not bear a prescription legend. We may provide further comments to you regarding adequacy of directions for use for this device when your premarket notification is reviewed.

Your firm's 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 the manufacture, processing, packing, storage or distribution are not in conformance with the current good manufacturing practices as required by the Quality System Regulation under 21 CFR, Part 820. The deviations are as follows:

Failure to establish an adequate quality plan which defines the quality practice, resources, and activities relevant to the devices your firm designs and manufactures and to establish how the requirements for quality will be met. 21 CFR § 820.20. No quality plan has been established or written for the reprocessing of single use devices such as the limb sleeve compression garments that your firm manufactures. There are no written procedures for conducting management reviews and quality audits of the single-use devices (SUD) reprocessing process. Quality audits of the SUD reprocessing process have not been conducted. Your firm's Quality Manual does not address reprocessed SUDs.

Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. 21 CFR § 820.30. No design control procedures have been established or maintained for reprocessed single-use limb sleeve compression garments that your firm manufactures.

Failure to adequately validate processes where the results of the processes cannot be fully verified by subsequent inspection and test. 21 CFR § 820.75. For example, the [REDACTED] sterilization process used to sterilize devices your firm manufactures for [REDACTED] has not been adequately validated. The validation study has not been fully completed and documented, no bioburden studies were performed, and specific load configurations during the sterilization cycles have not been established or defined. Also, the packaging process has not been validated. There is no documentation to show that the device packaging provides a microbial barrier and maintains package closure and seal integrity after sterilization, handling, shipping and storage.

The cleaning process for used compression garments that are to be reprocessed is not validated. 21 CFR § 820.75. There is no documentation showing that validation was done. No validation protocols and validation summaries were written. The adequacy of the cleaning process has not been established. There are no written procedures for tests performed to determine if the devices are clean. In addition, not all tests that are performed are documented. Equipment used in the cleaning process has not been qualified.

Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. 21 CFR § 820.70. There are no written procedures for the reprocessing of single-use limb sleeve compression garments that your firm manufactures for [REDACTED]. For example, there are no written procedures for how the devices are to be sterilized and for testing the devices after they have been sterilized. In addition, there are no written procedures for the cleaning of the devices that your firm manufactures for [REDACTED].

Failure to establish and maintain adequate procedures for finished device acceptance and release to ensure that each production run, lot, or batch of finished devices meet acceptance criteria. 21 CFR § 820.80(d). For example, of [REDACTED] Device History Records reviewed by the FDA Investigator, eighteen (18) showed that reprocessed devices were released for distribution before the associated data and documentation of a signature authorizing the release was conducted.

Failure to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements. 21 CFR § 820.50. For example, procedures outlining actions the healthcare facilities should perform before shipping the used devices to your facility and procedures for shipping the used devices to your facility for reprocessing. Used single-use limb sleeve compression garments are sent to your firm directly from clients of [REDACTED] and there are no written contracts or agreements between your firm and [REDACTED] pertaining to the reprocessing of single use medical devices.

Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities. 21 CFR § 820.25. For example, personnel involved with the reprocessing of single-use medical devices have not received training in the safe handling of material that could be contaminated with blood borne pathogens.

You should take prompt action to correct these deviations. 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 assessing civil money penalties. Also, until these violations are corrected and the FDA has documentation to establish that such corrections have been made, federal agencies will be advised of the issuance of this warning letter so that they may take this information into account when awarding government contracts.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to Evelyn D. Forney, Compliance Officer, at the above letterhead address.

Sincerely,

  
Henry L. Fielden  
District Director  
Cincinnati District