

**VIA FEDERAL EXPRESS****WARNING LETTER**

FLA-00-19

January 6, 2000

Louis L. Rudt, President  
Visions in Endosurgery, Inc. Inc.  
413 Oak Place Bldg. 5-J  
Port Orange, Florida 32127

Dear Mr. Rudt:

We are writing to you because on November 29 through December 3, 1999 FDA Investigator R. Kevin Vogel inspected your facility in Port Orange, Florida and collected information that revealed serious regulatory problems involving your firm's reprocessing of medical devices.

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm reprocesses are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that devices that you reprocess 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, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

**QS Regulation/GMPs**

1. Failure of management with executive responsibility to conduct reviews of the quality system to determine its suitability and effectiveness at defined intervals as required by 21 CFR 820.20(c). For example, no management reviews have been conducted (FDA 483, Item #10).
2. Failure to conduct quality audits to assure the quality system is in compliance with established quality system requirements as required by 21 CFR 820.22. For example, no internal quality audits have been conducted and no documentation exists establishing what criteria is to be audited (FDA 483, Item #9).

3. Failure to validate or to establish, implement and maintain procedures for monitoring and controlling process parameters to ensure reprocessed devices can withstand and continue to meet specifications after additional EtO sterilization cycles as required by 21 CFR 820.75. For example, devices resterilized by EtO are not adequately tested for EtO residues, tensile strength, or other properties that degrade as a result of additional exposures to EtO. Devices susceptible to degradation include, but are not limited to, sutures, balloon catheters, and any device with small lumens (FDA 483, Item #s1 & 4).
4. Failure to validate or to establish, implement and maintain cleaning procedures to reprocess single-use devices (SUDs) as required by 21 CFR 820.75. For example, validated cleaning procedures have been started but not yet completed (FDA 483, Item #2).
5. Failure to develop, conduct, control and monitor production processes involving the reprocessing of single-use and reusable devices to ensure they meet specifications and their intended use as required by 21 CFR 820.70. For example, (a) there is no determination by pyrogen testing that reprocessed devices are pyrogen-free, and (b) there is no determination of the latex content of reprocessed devices and the effect of EtO residues, and the appropriate latex warning statement is not declared (FDA 483, Item #s 3(a) & (b)).
6. Failure to adequately validate or have validated the EtO sterilization cycle used by your contract sterilizer as required by 21 CFR 820.75. For example, empty chamber studies were not available, no audits have been conducted of the contract sterilizer, no bioburden study has been completed, no protocols for sterilization validations for 1998 and 1999 are available, lack of diagram to show placement of BIs during ½ cycles, no maximum transfer time from preconditioning to sterilizer is defined, and no validation was completed of in-house sterilization of packaged sutures using the [REDACTED] sterilizer (FDA 483, Item #s 5, 6 & 14).
7. Failure to adequately validate the [REDACTED] Impulse Sealer as required by 21 CFR 820.75. For example, no post sterilization studies of packaging was included in sealer validation, no assurance the sealer bar maintains a uniform temperature, and the number of packages included in sealer validation is not statistically relevant to show it can consistently meet established specifications (FDA 483, Item #7).
8. Failure to validate the EtO aeration room as required by 21 CFR 820.75. For example, three aeration cycles and testing were not completed incorporating worst case testing of the various devices such as non-foil sutures, or latex containing devices (FDA 483, Item #8).

9. Failure to control product that fails to conform to specified requirements as required by 21 CFR 820.90. For example, no in-process reject monitoring is conducted (FDA 483, Item #11).
10. Failure to validate all clean room parameters as required by 21 CFR 820.75. For example, particulate testing of the Class 10,000 and Class 100,000 areas were not completed under worst case conditions, i.e., maximum number of personnel present during validation (FDA 483, Item #12).
11. Failure to establish procedures identifying training needs to ensure that all personnel are trained to adequately perform their assigned duties as required by 21 CFR 820.25(b). For example, there is no documentation describing how personnel obtained the knowledge to reprocess or test single-use devices (FDA 483, Item #3(C), and the minimum number of successful processes to be accomplished are not established and documented during training qualification of personnel (FDA 483, Item #13).
12. Failure to develop and document written procedures that define and control all manufacturing processes as required by 21 CFR 820.70. For example, reprocessing operations began in 1997 and written procedures were not established and approved until 1998 and 1999. Some procedures such as cleaning of devices still are not properly documented (FDA 483, Item #15).
13. Failure to establish and maintain a Quality Manual as required by 21 CFR 820.5. For example, SOP's for various operations, including but not limited to, Training, Corrective and Preventive Action, Management Responsibility and Design Control, have not been established, approved for use and implemented (FDA 483, Item #16).
14. Failure to establish and document the devices that are appropriate for reprocessing as required by 21 CFR 820.820.20(d). For example, a list of devices available to customers advising them of the products that VIE can reprocess, includes battery-operated suction/irrigation systems, disposable laparoscopes, and spinal endoscopes, is erroneous because VIE actually cannot reprocess these devices for lack of validated procedures. Furthermore, there is no established criteria for devices that will be accepted for reprocessing including product that is opened but unused or that is expired (FDA 483, Item #s18 & 19).
15. Failure to establish and maintain written Medical Device Reporting (MDR) procedures as required by 21 CFR 803.17 (FDA 483, Item #20).

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16. Failure to adequately label reprocessed devices as required by 21 CFR 820.120(a). For example, appropriate directions for use are not included in reprocessed device labeling (FDA 483, Item #21).
17. Failure to establish appropriate expiration dates of products whose quality deteriorates over time beyond acceptable fitness for use as required by 21 CFR 820.160(a). For example, there has been no determination that expiration dates on original packaging covers the device or the sterilization and packaging of the device; and expiration dates have either not been placed on reprocessed devices or arbitrary dates without substantial testing and support have been assigned (FDA 483, Item #3(D)).

#### **DESIGN CONTROL REGULATIONS [21 CFR 820.30(i)]**

Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before implementation as required by 21 CFR 820.30(i). For example, design changes to labels and packaging of reprocessed devices, and to a pin involving ██████████ scalpels made in response to a consumer complaint, were not followed (FDA 483, Item #17).

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of 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 FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective 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 QS regulation deficiencies are reasonably related will be cleared 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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations 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. Further, annotations to the Inspectional Observations (FDA 483) state that corrections will be accomplished beginning March 30, 2000 up through October 30, 2000. These timeframes are excessive.

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Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating 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.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,



Edward R. Atkins  
Acting Director  
Florida District