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**VIA FEDERAL EXPRESS**Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751**WARNING LETTER**

FLA-01-10

November 8, 2000

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

Dear Mr. Rudt:

During an inspection of your establishment located in Port Orange, Florida on September 26 through October 5, 2000, FDA Investigator R. Kevin Vogel determined that your establishment reprocesses various medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated 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 for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm's management review process failed to correct major deficiencies in your Quality System as required by 21 CFR 820.20(c). For example, major deficiencies of the Quality System identified during previous FDA inspections dated November 29 – December 3, 1999 and June 27, 2000 were not addressed (FDA 483, Item #11).
2. Your firm's internal quality audits failed to assure the quality system is in compliance with established quality system requirements as required by 21 CFR 820.22. For example, internal quality audits conducted on June 26, 2000 failed to identify all required areas covered by the QS Regulation or continuing deficiencies, e.g., document controls, purchasing controls, corrective and preventive actions (CAPA), production & processing controls and design controls (FDA 483, Item #10).

3. Your firm failed to validate or to establish, implement and maintain procedures for monitoring and controlling process parameters to ensure reprocessed devices can withstand and meet specifications after additional reprocessing cycles, including cleaning and sterilization by EtO as required by 21 CFR 820.75. For example, devices that are the most difficult to clean are not included in the cleaning validation, device validation/verification fails to assure that areas within devices that are not visible are adequately cleaned or that remaining material does not pose a health hazard, device validation does not include worst case conditions, there is no documentation to show that materials used to contaminate devices for validation are equivalent to contaminants received on devices after actual use, bioburden has not been determined, temperatures and concentrations of cleaning solutions are not controlled and monitored for optimum use and safety, deionized water is not adequately monitored nor is its effect on cleaning and validation, cleaning validations are not specific enough to ensure all devices or group of devices are adequately cleaned (FDA 483, Item #s 1 & 2).
4. Your firm failed to validate the number of times each device or family of devices can be reprocessed as required by 21 CFR 820.75. For example, Complaint #00-001 dated June 6, 2000 requested that flexible biopsy forceps not be reprocessed more than three times due to the device failing to grasp as tightly as required (FDA 483, Item #3).
5. Your firm failed 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, after a recent evaluation of devices that your firm reprocesses, you were unable to assure that the devices met all specifications as they were intended. You do not have an up-to-date listing of devices that you are able to accept and reprocess based on your firm's capabilities. There is no determination by testing that reprocessed devices are pyrogen free for both single-use devices and opened/unused device kits, both of which are labeled by the original equipment manufacturer and VIE that they are pyrogen free (FDA 483, Item #s 6 & 7).

6. Your firm failed to adequately validate or have validated the EtO sterilization cycles used by your contract sterilizer as required by 21 CFR 820.75. For example, you fail to validate opened/unused devices to assure they can withstand repeated EtO sterilizations. You fail to determine and document what devices or family of devices are most difficult to sterilize, criteria used to audit your contract sterilizer is not available, complete validation of the aeration room has not been completed, testing of EtO residues involving worst case devices was not conducted, protocols for sterilization validations are incomplete, and bioburden studies prior to and after cleaning are incomplete (FDA 483, Item #s 4 & 5).
7. Your firm failed to adequately validate the Fuji Impulse Sealer as required by 21 CFR 820.75. For example, the Fuji Impulse Sealer was not calibrated in accordance with a yearly written schedule even though it has been in operation for three years. Recent attempts to conduct operational and performance qualification of this equipment failed because the calibration of the equipment was not adequate and no records were available documenting the validation results (FDA 483, Item #9).
8. Your firm failed 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 except for laser delivery bundles (FDA 483, Item # 14).
9. Your firm fails to have and conduct an adequate corrective and preventive action (CAPA) program as required by 21 CFR 820.100. For example, reported non-conformities or complaints reference reprocessed devices that fail to operate in accordance with specifications or intended use. One complaint references a flexible biopsy forceps that will not grip tightly after being reprocessed more than three times, a complaint that reports a burr was not sharp and a report of a saw blade puncturing the packaging. There was no record of the corrective and preventive actions that were taken to verify the complaint or to effect correction (FDA 483, Item #12).
10. Your firm failed to establish and maintain procedures to ensure that all purchased or otherwise received product or services conform to specified requirements as required by 21 CFR 820.50. For example, shrink tubing provided by your supplier was the wrong size and the discrepancy was not discovered until it was required during processing (FDA 483, Item #13).

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11. 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 for each specific device (FDA 483, Item #16).
12. Your firm fails to document in the Device History Record (DHR) specific methods used to process each device that is reprocessed as required by 21 CFR 820.184. For example, cleaning methods used during reprocessing, the number of rewashes to which each device can be subjected, and the complete documentation demonstrating that each device was adequately processed (FDA 483, Item #18).

Several of the Inspectional Observations including FDA 483, Item #s 1, 2, 4, 5, 6, 7, 14, 16, & 17 were listed during previous inspections of your firm as noted above. Corrections for these observations were promised, however, they were determined not to have been corrected. Your planned corrective actions need to address not only the recent observations but those noted previously and all systems related to the Quality Systems regulation.

Your firm's written responses dated October 19 and November 2000 to the Inspectional Observations (FDA 483) issued to you on October 5, 2000 have been reviewed and will be made of the Florida District files.

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 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.

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In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contract, and to resume marketing clearance, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that they have conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QS regulation/GMPs (21 CFR Part 820). You should also submit a copy of the consultant's report, and your certification that you have reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Date and certification of initial audit by consultant and firm (to be conducted within six (6) months of the receipt of this letter).
- Monthly reports and timeline of progress to achieve compliance to be submitted by the last day of each month until all corrective actions have been corrected not to exceed 12 months.
- Final certification of accomplished corrective and preventive actions related to this Warning Letter to be submitted no later than November 1, 2001.
- An annual certification and a report of an annual audit by an outside consultant for each of the next two years covering your firm's current status with regard to the Quality Systems regulation.

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.

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.

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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,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is written in a cursive style with a horizontal line at the end.

Emma R. Singleton  
Director, Florida District