



m2809n

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

**PURGED** *PK*

July 27, 1999

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 99-36

Thomas C. Barthel  
President and CEO  
Clarus Medical Systems, Inc.  
1000 Boone Avenue North  
Minneapolis, Minnesota 55427

Dear Mr. Barthel:

We are writing to you because on June 8-18, 1999, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the LASE and SpineScope endoscopes that are manufactured at your facility in Minneapolis, MN.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. They are medical devices as defined by Section 201(h) of the Act.

Our inspection found that the devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of the medical devices are not in conformance with the Good Manufacturing Practices (GMP) requirements set forth in the Quality System Regulations for Medical Devices as prescribed by Title 21, Code of Federal Regulations (CFR), Part 820.

Page Two

Thomas C. Barthel  
July 27, 1999

Our inspection found your products are in violation of the law because of:

1. Failure to follow established procedures for receiving, reviewing, and evaluating complaints by a formally designated unit (21 CFR 820.198). Specifically:

- A. The customer complaint and returned material procedures for complaints involving the possible failure of a device were not followed for complaints, e.g. complaints RMA 753200, 75600, 7554000, 750500, 750300, 751500, and 754800. There is no documentation of the evaluation, follow-up investigation, and MDR status of the complaints;

- B. There are no records of the investigation into the complaints and reply letter to the customer for complaints RMA 752600, 754800, 751200, 750500, and 75700.

2. Information on identified quality problems and corrective and preventive actions has not been reviewed by Management [21 CFR 820.100(a)(7)]. Specifically, the frequent breakage of the  in the Spine Scope product line has not been reviewed by management.

3. Appropriate procedures have not been established for controlling environmental conditions [21 CFR 820.70(c)] in that these procedures do not specify the parameters for monitoring the microbial load of the controlled area and there is no designated upper limit for the bioburden level.

4. Sampling plans, i.e., the sampling plan for monitoring the sealing operation, are not based on valid statistical rationale [21 CFR 820.250(b)].

5. Process validation/verification activities have not been fully documented [21 CFR 820.75(a)] in that the qualification data for the model   Sealer and  sealer indicates does not explain why the final process parameters were selected.

Page Three

Thomas C. Barthel

July 27, 1999

6. Procedures for controlling the storage of product in storage areas and stock rooms are not adequate to ensure that no obsolete, rejected, or deteriorated product is distributed [21 CFR 820.150(a)] as evidenced by the storage of expired glues with non-expired glues in the production material storage room.
7. Quality audits have not been conducted to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system [21 CR 820.22]. Specifically:
  - A. The internal audit procedure calls for *~~~~* audits. The audits scheduled for the last *~~~~* of 1998 and first *~~~~* in 1999 have not been accomplished;
  - B. Quality re-audit was not performed to verify the corrective and preventive action recommended pursuant to the February 1998 audit;
  - C. The audit report for the February 1998 audit was not reviewed by the appropriate management representative.

In legal terms, the products are adulterated under section 501(h) of the Act.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

The specific violations noted in this letter and in the form FDA-483 issued at the close-out 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.

Page Four

Thomas C. Barthel  
July 27, 1999

If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We have received your written response dated July 14, 1999, responding to the form FDA-483 that was issued to your firm on June 18, 1999. Your responses are noted and are being made part of the official file. We note that items 8-12 on the form FDA-483 have not yet been addressed, but that corrective action was promised by September 20, 1999 (items 8-11), and August 23, 1999 (item 12), as annotated on the form FDA-483 during the close-out interview.

We would like to point out that the procedures for complaint handling and audits that existed at the time of the inspection were not followed. Training of affected employees and implementation of all new written procedures are an integral part of achieving effective correction.

Your responses to the specific items will be evaluated during our next scheduled inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As CEO, the most responsible individual at Clarus Medical Systems, Inc., it is ultimately your responsibility to ensure that devices designed, developed, and marketed at your facility in Minneapolis, MN, are in compliance with each requirement of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa, Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, MN 55401.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of Quality System Requirements for your devices and does not necessarily address other obligations you have under the law. You may obtain

Page Five

Thomas C. Barthel  
July 27, 1999

general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800)638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,



James I. Roberts  
Acting Director  
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 6/18/99