



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

PURGED

August 31, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 49

Albert Emola
President
Flexmedics Corporation
12400 Whitewater Drive, Suite 2040
Minnetonka, Minnesota 55343

Dear Mr. Emola:

We are writing to you because on June 25 through July 10, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the guidewires that are manufactured at your facility in Minnetonka, 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.

The law requires that manufacturers of medical devices adhere to Quality System Regulations for Medical Devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820, in the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of medical devices.

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

1. Failure to validate processes to a high degree of assurance and approve them according to established procedures where the results of a process cannot be fully verified by subsequent inspection and test (21 CFR 820.75, FDA-483 items 1, 2, 4, and 8), in that process validations were not performed on the . Additionally, Engineering Change Orders (ECOs) 3007 and 1790 changed processing parameters without validation having been performed. The EtO validation report does not describe what constituted the "dummy load" for the half and full cycle runs.
2. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications [21 CFR 820.70(a), FDA-483 item 3] in that the firm allows the   beyond the specified limits without documenting when this is done or the amount
3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints (21 CFR 820.198, FDA-483 item 5) in that complaints and Field Experience Reports (FER) include multiple devices and part numbers. The number of complaints included in the complaint trending does not always match those in FER for the corresponding time periods due to monitoring grouped complaints as a single complaint/failure.
4. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements (21 CFR 820.50, FDA-483 item 7) in that the approved vendor list (AVL) does not include part numbers added to devices since September 1997. Received product is accepted without checking the approved vendor list (AVL) and the Quality Engineer is not always contacted when a vendor does not appear on the AVL as required by the firm's own standard operating procedure for receiving.

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5. Failure to establish and maintain procedures for implementing corrective and preventive action (21 CFR 820.100, FDA-483 item 6) in that device history record for encapsulated guidewire lot 514503 showed that the lot was re-worked without initiating a review and approval ~~as required by Manufacturing Procedure #103566.~~

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

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president, the most responsible individual at Flexmedics Corporation, it is ultimately your responsibility to ensure that devices manufactured at your facility in Minnetonka, 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

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know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

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 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 A. Rahto
Director
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 7/10/98