

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

**PURGED** (24)

January 7, 1997

cc: HFI-35/FOI Staff  
DWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 97-23

Brian K. Evenson  
President  
McKechnie Plastic Components  
7309 West 27th Street  
Minneapolis, Minnesota 55426

Dear Mr. Evenson:

During an inspection of your firm located in Minneapolis, MN, concluded on December 16, 1996, our Investigator determined that your firm manufactures Microvascular Anastomotic System (MAS) devices. MAS are 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 Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. The sterilization process for the MAS rings has not been re-validated since the operation was moved.
2. The written agreement between McKechnie Plastic Components and has not been signed.

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3. The shipping cartons used to transport the MAS devices to are not labeled as non-sterile.
4. The manufacturing process for the MAS device has not been qualified.
5. The test procedure for a peel test according to DHR 80-5235 has not been completed.
6. Standard operating procedures used in the production area have pen-and-ink changes which have not received the benefit of engineering change order controls.
7. The final inspection test procedure was not followed for lot #100 G.

Please refer to the FDA-483 issued on December 16, 1996, for a more complete listing of the adverse findings. We acknowledge that FDA-483 items 2 and 7 were corrected and verified prior to concluding this inspection.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of Section 502(a) of the Act in that the shipping cartons to Isomedix are not labeled as non-sterile devices and the contract with Isomedix is unsigned.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. 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.

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 pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have

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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.

Please notify this office in writing within 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 identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely yours,



John Feldman  
Director  
Minneapolis District

TPN/ccl