



m3673n

**PURGED**

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

April 18, 2000

**WARNING LETTER**

x6: HFI-35  
DWA

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

Refer to MIN 00 - 29

John J. Booth  
Chief Executive Officer  
Microvena Corporation  
1861 Buerkle Road  
White Bear Lake, Minnesota 55110

Dear Mr. Booth:

We are writing to you because on March 2-14, 2000, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the amplatz thrombectomy devices that you manufacture.

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. Amplatz thrombectomy devices 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 Practice (GMP) requirements set forth in the Quality System Regulations for Medical Devices as prescribed by Title 21, Code of Federal Regulations, Part 820 (21 CFR 820).

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

1. Failure to perform design validation under defined operating conditions on initial production units, lots, or batches, or their equivalents [21 CFR 820.30(g); form FDA-483 item 2].

Page Two

John J. Booth  
April 18, 2000

2. Failure to review, update, and approve plans as design and development evolves [21 CFR 820.30(b); form FDA-483 items 1 and 3].
3. Failure to implement procedures to address the identification, documentation, evaluation, and disposition of nonconforming product [21 CFR 820.90(a); form FDA-483 item 4];
4. Failure to identify the actions needed to correct and prevent recurrence of nonconforming product and other quality problems [21 CFR 820.100(a)(3); form FDA-483 item 5].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As Chief Executive Officer, the most responsible individual at Microvena Corporation, it is ultimately your responsibility to ensure that devices manufactured at your facility in White Bear Lake, Minnesota, are in compliance with each requirement of the Act and regulations.

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

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. Additionally, no pending applications for pre-market approval (PMA's) or export approval requests will be approved and no pre-market notifications (Section 510(k)'s) will be found to be substantially equivalent for products manufactured for your facility until the violations have been corrected.

We received your letter dated March 28, 2000, responding to the form FDA-483 issued on March 14, 2000. Although the response promises correction of the items referenced in the form FDA-483, it does not adequately address all our concerns. You have not justified that design validation results are valid for the production units.

Page Three

John J. Booth  
April 18, 2000

Your responses to the specific items will be evaluated by inspection to verify that the procedures and documentation referenced in your response to the form FDA-483 have been effectively implemented.

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 Acting Compliance Officer Michael W. Roosevelt 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 current Good Manufacturing Practices 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/cdrh/>.

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. Roosevelt at (612) 334-4100 ext. 124.

Sincerely,



James A. Rahto  
Director  
Minneapolis District

MWR/ccl

Enclosure: Form FDA-483, 3/14/00