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

March 9, 2001

**WARNING LETTER**

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

**Refer to MIN 01 - 41**

Robert G. Dutcher  
President and Chief Executive Officer  
Possis Medical, Inc.  
9055 Evergreen Boulevard NW  
Minneapolis, Minnesota 55433-8003

Dear Mr. Dutcher:

During an inspection of your establishment located in Minneapolis, MN, on January 4 - February 7, 2001, our investigators determined that your establishment manufactures thrombectomy catheter systems which 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 Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820). Examples include:

1. Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization (21 CFR Part 820.20). See item #1 in the Form FDA-483 issued to you on February 7, 2001 (copy enclosed).
2. Adequate resources have not been provided for performing work and assessment activities [21 CFR Part 820.20(b)(2)]. See item #2 in the Form FDA- 483.
3. The procedures for corrective and preventive actions were not implemented [21 CFR Part 820.100(a)]. See item #3 in the Form FDA-483.

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4. Process validation activities are not complete and/or the results have not been fully documented [21 CFR Part 820.75(a)]. See item #4 in the Form FDA-483.
5. Procedures for monitoring and control of a validated process are incomplete and have failed to ensure that specified requirements are consistently met [21 CFR 820.75(b)]. See item #5 in the Form FDA-483.
6. The review of sampling methods for adequacy for their intended use was not documented [21CFR 820.250(b)]. See item #6 in the Form FDA-483.
7. A complaint involving the possible failure of a device to meet specifications was not fully investigated [21 CFR 820.198(c)]. See item #7 in the Form FDA-483.

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 Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). You also must promptly initiate permanent corrective and preventive action in your quality system.

We have received your February 22, 2001, letter responding to the Form FDA-483 issued on February 7, 2001. The response describes your plans for correction of the deficiencies in your quality system. Your response correctly recognizes and acknowledges that many of your quality system problems are systemic. The corrective actions that you propose, if completed and implemented in a timely manner, appear to be adequate. However, a follow-up inspection will be conducted to fully determine the adequacy of your corrections.

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 Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Please note that some of the quality system deficiencies found during the January 4-February 7, 2001, inspection are the same or similar to deviations cited during a previous inspection conducted on January 6, 7 and 11-14, 2000. Those deficiencies were brought to your attention in a post-inspection letter dated February 7, 2001 (copy enclosed).

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You should take prompt action to bring your quality system into compliance. Failure to promptly correct these quality system deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 working days of receipt of this letter of the specific steps you will be taking to comply with our request.

Your response should be sent to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,



David R. Yost  
Acting Director  
Minneapolis District

TGP/ccl

Enclosure: FDA-483, 2/7/01  
Rahto to Dutcher, 2/7/00