



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
Rockville MD 20857

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10/14/98  
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OCT 14 1998

Federal Express

WARNING LETTER

Marc Glickman, M.D.  
Virginia Vascular Associates  
880 Kempsville Road  
Norfolk, Virginia 23502

Dear Dr. Glickman:

On July 20-30, 1998, by Ms. Nancy Haas, an investigator with the Food and Drug Administration (FDA), Baltimore District Office, Norfolk Resident Post, conducted an inspection at your facility. The purpose of that inspection was to determine whether your activities and procedures as principal investigator of an investigational study of the Possis Medical Inc. [ ] complied with applicable regulations. This product is a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

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We have evaluated the inspection report submitted by the District Office which revealed that there were violations of the requirements of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions, and Part 50 - Protection of Human Subjects. These items were presented to you as observations on form FDA-483 and discussed with you at the conclusion of the inspection. The following is a list of violations from the referenced regulations found during the inspection. It is not intended to be an all-inclusive list of deficiencies with regard to your clinical study.

1. Failure to conduct the investigation in accordance with the investigational plan, conditions of approval imposed by the IRB, sponsor's investigator agreement, and applicable FDA regulations as required by 21 CFR 812.100.

You failed to follow the study protocol as follows:

[ ]

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compression time will be reduced by one minute each time the graft is accessed as long as no bleeding is detected. If bleeding occurs, compression will be extended by one minute for the next access." Your case report forms reveal the dialysis centers decreased the compression time for 13 subjects even though the subject experienced bleeding after compression at the previous dialysis. In addition, it appears that the initial puncture site compression time duration block on the routine hemodialysis forms were filled out in advance by the dialysis center personnel and used as a schedule rather than to record the actual compression duration.

c. Review of your subject's case report forms revealed that [

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In addition, you failed to obtain Institutional Review Board (IRB) approval for significant protocol changes as required by 21 CFR 812.42. For example, the [

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IRB approval prior to its implementation. No documentation required by 21 CFR 812.140(a)(1) of submission to and approval of this amendment by the Eastern Virginia Medical School and Chesapeake General Hospital IRBs could be located during this inspection.

2. Failure to maintain accurate and complete study records in accordance with 21 CFR 812.140.

[ ]

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3. Failure to keep accurate records of the receipt, use, or disposition of the investigational device as required by 21 CFR 812.140(a)(2).

[ clinical site.

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Device accountability records were not maintained at your site until [

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It is your responsibility to ensure that any future investigational studies will be conducted in accordance with applicable regulations.

Within fifteen (15) working days of receipt of this letter please provide this office with written documentation of any specific steps you have taken or will be taking to bring any future studies into compliance with FDA regulations.

You should direct your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch I, 2098 Gaither Road, Rockville, Maryland 20850, Attention: Alice Rozema. A copy of this letter has been sent to Baltimore District Office. We request that your response also be sent to that office at Food and Drug Administration, Baltimore District Office, 900 Madison Avenue, Baltimore, Maryland 22046.

Please direct all questions concerning this matter to Ms. Rozema at (301) 594-4720, ext. 131.

Sincerely yours,



Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices  
and Radiological Health