DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2123M

Food and Drug Administration
Rockville MD 20857

FOI purged 10/14/98 ogr

OCT 14 1998

Federal Express

WARNING LETTER

Mark Odland, M.D.
Hennepin County Medical Center
Vascular Access Unit
825 South 8th Street
Minneapolis, Minnesota 55401

Dear Dr. Odland:

Between August 10 and 25, 1998, Ms. Jennifer Vollom, an investigator with the Food and Drug Administation (FDA), Minneapolis District Office, 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 (21CFR), Part 812 - Investigational Device Exemptions (IDE). These items were presented to you as observations on form FDA-483 and were discussed with you at the conclusion of the inspection. The following description of violations 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, 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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The collection [redacted]. There is no documentation that [redacted] were trained to follow the protocol and no documentation that corrective [redacted] failed to follow the protocol in [redacted] failed to have specific procedures performed.

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[redacted] protocol, with no Variation or Violation form completed.

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

There was no consistent method for collecting, documenting and/or [redacted]. For example, "General [redacted] /or [redacted]

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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).

No accountability records were maintained documenting the date of receipt and quantity of [redacted]. the dates and quantity dispensed, and the dates/quantity returned to the sponsor.

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It is your responsibility to ensure that any future investigational studies will be conducted in accordance with applicable regulations. FDA acknowledges your verbal responses to the field investigator regarding these violations. However, a written response is requested.

Within fifteen 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 the Minneapolis District Office. We request that a copy of your response also be sent to that office at Food and Drug Administration, Minneapolis District Office, 240 Hennepin Avenue, Minneapolis, Minnesota 55401.

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

Sincerely yours,

Michael E. Marcarelli

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