



U.S. Department of Health & Human Services



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Inspections, Compliance, Enforcement, and Criminal Investigations

Stuart Harlin, Md



Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

WARNING LETTER

VIA UPS EXPRESS

JUL 21 2010

Stuart A. Harlin, M.D.
Clinical Investigator
Coastal Vascular & Interventional, PLLC
5147 N. 9th Ave., Suite 318
Pensacola, FL 3250

Dear Dr. Harlin:

This Warning Letter is to inform you of objectionable conditions observed during the Food and Drug Administration (FDA) inspection conducted at your clinical site from May 17 to May 21, 2010 by an investigator from the FDA Florida District Office. The purpose of this inspection was to determine whether activities and procedures related to your participation in the clinical study "Suprarenal Proximal Cuff Study," Investigational Device Exemption (IDE) G990139, and "UNITE LeMaitre Vascular UniFit Aorto-Uni-iliac Stent Graft Clinical Study," IDE (b)(4), complied with applicable federal regulations. The Suprarenal Proximal Cuff and the UniFit Aorto-Uni-iliac Stent Graft is a device as that term is defined in section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321 (h). This letter also requests prompt corrective action to address the violations cited and discusses your June 4, 2010 written response to the noted violations.

The inspection was conducted under a program designed to ensure that data and information contained in requests for IDEs, Premarket Approval (PMA) applications, and Premarket Notification submissions (510(k)) are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Our review of the inspection report prepared by the district office revealed several violations of Title 21, Code of Federal Regulations (21 CFR) Part 812 -Investigational Device Exemptions and Part 50 -- Protection of Human Subjects. At the close of the inspection, the FDA investigator presented an inspectional observation Form FDA 483 for your review and discussed the observations listed on the form with you. The deviations noted on the Form FDA 483, your written response, and our subsequent review of the inspection report are discussed below:

Failure to conduct an investigation according to the signed agreement, the investigational plan, and FDA regulations. [21 CFR 812.100 and 21 CFR 812.110(b)]

An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, investigational plan, FDA regulations, and any conditions of approval imposed by an IRS. Examples of your failure include, but are not limited to the following:

- The LeMaitre and Endologix protocols require CT scans pre-procedure and 1 month, 6 months, and 1-5 years annually post-procedure. However, subjects (b)(4), (b)(4), and (b)(4) did not receive the protocol required CT scans, which assess endoleaks, aneurysm size, device migration, and device integrity, at the 6-month and/or 1-year follow-up visit.

- The sponsor was notified on August 24, 2008 of subject **(b)(4)**, which occurred on June 19, 2008. The LeMaitre protocol requires the investigator to report all serious adverse events (SAEs) to the sponsor within 24 hours of discovery.

Your response states that you have created a separate clinical trial section in your own practice to ensure such discrepancies are not present and that your group will work closely with all ongoing trials to ensure the safety of your patients and the integrity of your data. Your response is inadequate in that it does not describe the duties and qualifications of the staff working in the separate clinical trial section, provide the standard operating procedures they follow or confirm that the staff have received training on the protocols from each ongoing clinical trial. Please submit documentation with your response that provides this information.

Failure to maintain accurate and complete records of each subject's case history and to maintain required records for a period of 2 years after the date on which the investigation was terminated. [21 CFR 812.140(a)(3) and (d)]

A participating investigator shall maintain accurate, complete, and current records of each subject's case history and exposure to the device and the required records during the investigation and for a period of 2 years after the latter of the following two dates: the date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application. Examples of your failure include, but are not limited to the following:

LeMaitre Protocol LMV-AUI-P2-001

- The Case Report Form (CRF) for subject **(b)(4)** documents the order date and measurements for the custom study device; however, order date and measurements are left blank on the source document.
- The CRF for subject **(b)(4)** shows that ballooning was required during the procedure; however, this information is left blank on the source document.

Endologix Protocol 04-002

- At the time of inspection, there were no signed and dated informed consent forms (ICF) for subjects **(b)(4)** and **(b)(4)**, though informed consent was obtained.
- For subjects **(b)(4)**, **(b)(4)**, and **(b)(4)** there were no source documents for the pre-procedure, procedure, and discharge visits and no source document for the 1-month visit for subject **(b)(4)**.

Your response states that in the future all clinical research will be hosted inhouse where there will be greater control as well as following protocols implemented by Coastal Vascular & Interventional, PLLC. Your response is inadequate in that you have not provided these newly implemented protocols. Please provide the protocols and dates of implementation and a list of dates when study personnel have been trained or will be trained.

In your response, you submitted copies of the ICFs for subjects **(b)(4)** and **(b)(4)**. We also acknowledge that you have submitted a request to Sacred Heart Hospital Medical Records for all source material that is available for the noted visits of "subjects **(b)(4)**, **(b)(4)**, and **(b)(4)**," in order to maintain a complete set of records as required. Please provide copies of the information for subjects **(b)(4)**, **(b)(4)**, and **(b)(4)** when received.

Failure to submit a timely report of withdrawal of Institutional Review Board approval to the sponsor. [21 CFR 812.150(a)(2)]

An investigator shall report to the sponsor within 5 working days, a withdrawal of approval by the reviewing Institutional Review Board (IRB) of the investigator's part of an investigation. An example of your failure is as follows:

- The IRB terminated approval of the LeMaitre Vascular study, Protocol LMV-AUI-P2-001, on December 11, 2009. However, this termination was not reported to the sponsor until January 12, 2010.

Your response states that you will follow all FDA guidelines according to 21 CFR and that your firm has educated and will continue to educate all personnel involved with clinical trials on Good Clinical Practice. Please describe in detail, the training that has been or will be provided and when instructors and individuals have or will be trained. Please also describe how the remaining subjects in these studies will be followed for the time required by the protocols and identify the IRB that will oversee the follow up phase of the study.

The violations described above are not intended to be an all inclusive list of problems that may exist with your clinical study. It is your responsibility as a clinical investigator to ensure compliance with the Act and applicable regulations.

Within fifteen (15) working days of receiving this letter, please provide written documentation of the additional actions you have taken or will take to correct these violations and prevent the recurrence of similar violations in current or future studies for which you are the clinical investigator. In addition, please provide a complete list of all clinical trials in which you have participated for the last five years, including the name of the study and test

article, the name of the sponsor, the number of subjects enrolled, and the current status of the study. Failure to respond to this letter and take appropriate corrective action could result in the FDA taking regulatory action without further notice to you. In addition, FDA could initiate disqualification proceedings against you in accordance with 21 CFR 812.119.

You will find information to assist you in understanding your responsibilities and planning your corrective actions in the **FDA Information Sheets Guidance for Institutional Review Boards and Clinical Investigators**, which can be found at <http://www.fda.gov/oc/ohrt/irbs/>¹. Any submitted corrective action plan must include projected completion dates for each action to be accomplished.

Your response should reference "CTS # G990139/E002" and be sent to:

Attention: Anne T. Hawthorn, J.D.
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Bioresearch Monitoring
10903 New Hampshire Avenue
Building 66, Room 3504
Silver Spring, Maryland 20993-0002.

A copy of this letter has been sent to the FDA Florida District Office, 555 Winderley Place, Suite 200. Please send a copy of your response to that office.

The Division of Bioresearch Monitoring has developed introductory training modules in FDA regulated device clinical research practices, which are available on the FDA website. The modules are for persons involved in FDA regulated device clinical research activities. These modules are located at the following website address: <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm>².

If you have any questions, please contact Anne T. Hawthorn, J.D., at (301) 796-6561 or Anne.Hawthorn@fda.hhs.gov.

Sincerely yours,

/S/

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

cc:

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Links on this page:

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm220637.htm>

1. <http://www.fda.gov/oc/ohrtlirbs/>
2. <http://www.fda.gov/Training/CDRHLearn/ucm162015.htm>