



JUN 1 2004

Via Federal Express

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

Colette Cozean, Ph.D.
Chief Executive Officer and
Regulatory Consultant
Surgilight, Inc.
21581 Midcrest Drive
Lake Forest, CA 92630

Dear Dr. Cozean:

This Warning Letter informs you of the objectionable conditions found during the Food and Drug Administration (FDA) inspection conducted at your [REDACTED] site. This letter also discusses your written response to the noted violations and requests that you implement prompt corrective actions. Mr. Allen F. Hall, an investigator from the FDA's Los Angeles District Office conducted the inspection from December 18, 2003 through January 5, 2004. The purpose of the inspection was to determine whether your activities and procedures as a sponsor and monitor for the study entitled, "[REDACTED] for [REDACTED] ([REDACTED])" complied with applicable FDA regulations. The [REDACTED] is a device as that term is defined under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

This inspection was conducted under a program designed to ensure that data and information contained in Investigational Device Exemption (IDE) applications, Premarket Approval (PMA) applications, and Premarket Notification [510(k)] submissions are scientifically valid and accurate. The program is also designed 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 Los Angeles District Office revealed serious violations of Title 21, Code of Federal Regulations (21 CFR), Part 812 - Investigational Device Exemptions. At the conclusion of the inspection, Mr. Hall presented and discussed with you the observations listed on the Form FDA 483 "Inspectional Observations." The violations noted on the Form FDA 483, our subsequent review of the inspection report, and review of your response to the Form FDA 483 items are discussed below.

Failure to secure investigator compliance and ensure proper monitoring of the investigational study. 21 CFR 812.40 and 812.46.

Under FDA regulations, a sponsor is responsible for ensuring proper monitoring of device investigations. 21 CFR 812.40. A sponsor who discovers that an investigator is not complying with the investigational plan, signed agreement, applicable FDA regulations, or other conditions of approval imposed by the reviewing Institutional Review Board (IRB) or FDA must take steps to secure the investigator's compliance or discontinue shipments of the device to the investigator and terminate the investigator's participation in the study. 21 CFR 812.46.

Examples of your failure to satisfy these requirements include, but are not limited to, the following:

- While you were aware that investigators failed to adhere to the study protocol and the investigator agreements, you failed to take appropriate action to bring the investigators into compliance. For example, the protocol states that the maximum depth of the [REDACTED] incision should be maintained at approximately [REDACTED] of [REDACTED] thickness ([REDACTED] μ). Both investigators, however, made surgical incisions in excess of this prescribed depth.

On more than one occasion, you warned one of the investigators, Dr. [REDACTED], about this protocol deviation, but source records indicate that he continued making cuts in excess of [REDACTED]. You were aware of this continued protocol deviation, but took no additional action to bring him into compliance with the protocol. Your periodic monitoring reports, however, state that the protocol was being followed.

Your written response to FDA's inspectional observations, while acknowledging that Dr. [REDACTED] was warned about "excessive depth" cuts, also states that you believe that the depth of cut limit in the protocol should be interpreted as [REDACTED] ± [REDACTED] of [REDACTED] thickness. Even if the protocol is interpreted to allow for this degree of variability in incision depth, however, our records indicate that cuts were being made outside of the [REDACTED] ± [REDACTED] range. You, as the sponsor/monitor, must assure that investigators comply with the protocol as it is written. If you wish to make changes in the investigational plan (including the protocol), you should adhere to the procedures regarding supplemental applications described in 21 CFR 812.35(a).

As another example, one of the investigators treated a subject with a [REDACTED] that had failed internal calibration and was thereby outside the parameters/specifications of the protocol. The protocol states that the device should be used at [REDACTED] mJ/[REDACTED] Hz. One subject was treated with the device set at [REDACTED] mJ/[REDACTED] Hz for one [REDACTED] and [REDACTED] mJ/10 [REDACTED] for the other [REDACTED]. While you reported this incident to FDA in your next IDE report, we did not find documentation indicating that you took action to bring the investigator into compliance with the protocol.

- You also failed to secure investigator compliance with the requirements for obtaining informed consent. As a result, the investigators conducted pre-operative examinations before obtaining informed consent for several subjects. Two subjects also underwent pre-screening prior to signing the informed consent form, even though the investigator was instructed on the pre-screening sheet not to enroll a subject into the study if the consent had not already been completed.

While some types of screening evaluations may be conducted before informed consent is obtained, FDA regulations state that no investigator may involve a human being as a subject in research that is subject to FDA regulations on human subject protection unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. 21 CFR 50.20. For additional guidance on conducting screening tests before the enrollment of subjects in a study, you may find FDA's Guidance for IRBs and Clinical Investigators on this topic to be a useful resource:
<http://www.fda.gov/oc/ohrt/irbs/toc4.html#screening>.

In your written response to this Warning Letter, please identify how you plan to secure investigator compliance in obtaining informed consent and adhering to the protocol. If you are unable to secure investigator compliance, under 21 CFR 812.46(a) you should promptly discontinue shipments of the device to the investigator(s) and terminate the investigator(s)' participation in the investigation. Also under this regulation, you should require that the investigator(s) dispose of or return the device(s), unless this action would jeopardize the rights, safety, or welfare of subjects.

Failure to maintain and submit complete and accurate records of the progress of the study. 21 CFR 812.150(b)(5).

A sponsor must prepare and submit several types of reports specified in 21 CFR 812.150(b). For example, a sponsor must submit progress reports to all reviewing IRBs at least annually, and for significant risk devices, must also submit these to FDA. 21 CFR 812.150(b)(5). You failed to satisfy this annually reporting requirement because you failed to submit accurate progress reports to FDA.

Data tables submitted to FDA in your progress report dated [REDACTED], [REDACTED], contained numerous deviations from data contained in corresponding case report forms.

For instance, in the progress report you submitted to FDA, one subject was reported to have had a total of [REDACTED] mJ of energy exposure to the right [REDACTED] and another [REDACTED] mJ to the left [REDACTED], for a total of [REDACTED] mJ. However, the case report forms identify that [REDACTED] and [REDACTED] mJ respectively were used for a total of [REDACTED] mJ for both [REDACTED].

Similarly, in your progress report, another subject was reported to have had [REDACTED] mJ of energy exposure to the left [REDACTED]. However, the case report form identifies that [REDACTED] mJ was used for this subject's left [REDACTED].

The above listed violations are not intended to be an all-inclusive list of violations that may exist in your clinical study. It is your responsibility as the sponsor to ensure adherence to each applicable requirement of the Act and FDA regulations.

We also note that at the time of FDA's inspection, shipment and distribution records including the serial numbers and the quantity of the study devices were not consistently available at your site. In your response, you indicated that the records were obtained from your Florida office and that you will henceforth maintain these records on site to facilitate monitoring. It appears that this action will help you satisfy your responsibility as a sponsor to maintain accurate, complete, and current records of the shipment and disposition of investigational devices, including the names and addresses of consignees, the type and quantity of devices, dates of shipment, and batch numbers or code marks. 21 CFR 812.140(b)(2).

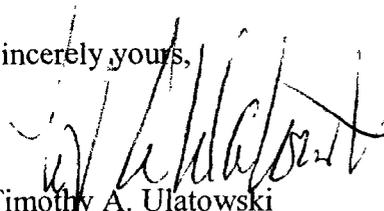
In addition to the above specified regulations regarding sponsor/monitor responsibilities, you should refer to the regulations in 21 CFR Part 812 regarding sponsor responsibilities.

We recognize that you have been working with the Office of Device Evaluation in FDA's Center for Devices and Radiological Health to implement corrective actions, and that your efforts to complete your corrective action plan are ongoing. This letter does not supercede the obligations you previously committed to in order to address data integrity concerns. You should continue to work with FDA to satisfactorily complete implementation of your corrective action plan and other responsibilities arising in connection with this study.

We are also sending a copy of this letter to FDA's Los Angeles District Office, 19701 Fairchild, Irvine, California 92612-2506. We request that you also send a copy of your response to that office. If you have any questions, please contact Mr. G. Levering Keely by phone at (301) 594-4723 ext. 142.

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 II, (HFZ-312), 2094 Gaither Road, Rockville, Maryland 20850, Attention: Mr. G. Levering Keely, BSN, MPA, Consumer Safety Officer.

Sincerely yours,



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