

procedures. This had not been intended by ODE and therefore specific requests for this indication were solicited from those who possessed approved IDEs and wished to continue performing bilateral procedures. The letter from Dr. Sterling reflects Dr. Nevyas' adherence to this request. However, according to Mr. Stokes, he was not shown a copy of this letter during his inspection of your Institute.

Another deviation noted was enhancement of a subject prior to approval of the retreatment supplement to the IDE. Dr. Morris Waxler confirmed that the policy of his division was to allow, upon request, enhancement of small numbers of subjects originally treated with an excimer laser prior to IDE approval. This was with the understanding that an official request for an IDE supplement for this indication would follow shortly. The inspection report notes that you stated that you thought the procedure was approved. It does not include mention of verbal permission from Dr. Waxler, as noted in the response.

With regard to issues related to informed consents, the response states that the subject who had not received a copy of the revision of the informed consent as approved by the Institutional Review Board (IRB) for simultaneous bilateral surgery has since been sent the addendum in question. Moreover, your staff has been instructed to assure that the proper informed consent is used and that each consent form contains a properly executed signature and date in both the subject and witness signature areas. These actions should prevent future problems in this area.

Use of the Summit laser at your Marlton, New Jersey site for off-label procedures is not included in your IDE protocol. Moreover, enhancements approved under your IDE do not include hyperopic procedures. It is therefore considered a protocol violation to retreat subjects of your IDE study using the Summit laser and performing hyperopic LASIK. There is a difference between subjects treated as part of an IDE study and patients treated in the normal course of your practice. It is the responsibility of the clinical investigator to make every effort to assure that the subjects enrolled in a study are aware of the investigational nature of the procedure from the start and the need for specific control of their treatment while they are participants in the study. Treatment of subjects with devices and/or procedures that are not included in the approved IDE are considered protocol violations. The hyperopic enhancement terminates the inclusion of the retreated subjects in the study.

Moreover, according to 21 CFR 812.150(a)(4), an investigator must notify the reviewing IRB of any deviation from the investigational plan in an emergency no later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the IRB is needed for changes to the protocol.