An Important Letter to Ophthalmologists
About Lasers for Refractive Surgery

Dear Doctor:

This is to provide an update on the Food and Drug Administration's (FDA) policies regarding lasers for refractive surgery. When we last wrote you on October 10, 1996, we described two situations in which unapproved lasers were being operated without FDA approval: (1) unapproved lasers manufactured by the owner, by someone else for the owner, or by a corporate entity ("black box" lasers); and (2) importation of Summit lasers originally manufactured in the United States and exported for use overseas, or manufactured overseas before the company had received FDA approval to market its devices in the U.S. ("gray market" lasers). We have new information for you with respect to both types of lasers.

First, we have uncovered through our own investigations what appears to be a pattern of serious patient injuries attributed to the use of some "black box" lasers. These include several injuries requiring corneal transplantation, additional (and repetitive) corneal surgery, severe night vision problems, and frequent overcorrections ($\geq +2.00$D). These injuries and overcorrections appear to be caused by a laser beam that has a relatively small optical zone, has considerable inhomogeneity, and produces a non-spherical ablation pattern.

The injuries from "black box" lasers demonstrate the importance of evaluating the safety and effectiveness of lasers for refractive surgery with a limited number of patients under an FDA-approved Investigational Device Exemption (IDE) and the oversight of an Institutional Review Board, as required by the Federal Food, Drug, and Cosmetic Act (the Act). Data from such studies is critical in establishing the risks and benefits of particular laser designs.

In addition, "black box" lasers may not have adequate fail-safe mechanisms and equipment hazard analyses; furthermore, software validation and verification may not have been performed. We therefore regard the use of unapproved lasers for refractive surgery as a serious public health problem.

Second, with respect to "gray market" lasers, many of the physicians who imported these lasers communicated their belief to the agency that their lasers were the same as the approved Summit lasers. FDA attempted, in the exercise of its enforcement discretion, to resolve the matter and accommodate these physicians by providing an opportunity for them to certify that their lasers were identical in all relevant aspects to approved lasers.

Our experience with certification has led us to conclude that the process described in our October 10 letter cannot be implemented legally. Because imported Summit lasers do not meet all of the conditions for approval of the Summit premarket approvals (PMAs), no imported Summit lasers may be considered to be covered by those PMAs unless the laser has been remanufactured by Summit to conform to the specifications of the company's approved lasers. Unapproved lasers used outside of an FDA-approved clinical trial violate the Act.

By now you are likely aware that FDA has seized "black box" lasers that have been illegally distributed and are being used without an approved IDE. We intend to take additional regulatory action against other unapproved "black box" and "gray market" lasers used in refractive surgery.

Both "black box" and "gray market" lasers for refractive surgery are unapproved Class III medical devices that can be used on patients only after FDA has approved an IDE for a clinical trial. Under an IDE, only a limited number of subjects with specific conditions may be treated. The IDE process is designed to investigate the safety and effectiveness of a device either to obtain information for publication or to generate the data needed to obtain marketing approval from FDA. An IDE is not an approval for the commercial treatment of patients. Any study conducted under an IDE is subject to all IDE regulations. You must understand, however, that the market approval process that follows completion of IDE studies requires more than clinical data; for example, the application also must include detailed engineering and manufacturing specifications.

Clinicians wishing to conduct a clinical trial of a refractive surgery laser can obtain information by visiting FDA's website at http://www.fda.gov/cdrh/ode/laser.html. Look for Document 2093. If you have further questions, contact Morris Waxler, Ph.D., at (301) 594-2018.

We know you share our concern that patients receive the safest treatment possible when undergoing refractive surgery with lasers, and we look forward to your cooperation in this matter. In addition, if you are aware of any patient injuries associated with the use of lasers for refractive surgery, we request that you report them to the FDA. You may report adverse events to FDA's MedWatch program at telephone 1-800-FDA-1088 or fax 1-800-FDA-0178.

Sincerely yours,

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