DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 13 1991

TO: ALL LASER PRODUCT MANUFACTURERS

SUBJECT: Criteria for Considering an Investigational Medical Laser Device as a Significant Risk Device

Background:

The sponsor of an investigation of any new medical device that exposes human subjects to the risk of serious injury must submit an application to the Food and Drug Administration (FDA) for an investigational device exemption (IDE). If, however, an investigation is considered by the sponsor and by an appropriate institutional review board (IRB) to involve no significant risk, then the sponsor may be considered to have an IDE under the abbreviated requirements of Section 812.2(b). A manufacturer may not deliver a new medical device to an investigator for use on human subjects without an IDE, either formally approved by FDA or deemed granted under the abbreviated requirements. FDA believes that some guidance is appropriate for manufacturers of laser products to enable manufacturers to ascertain the degree of risk and hence the extent of regulatory requirements.

Definitions:

Medical devices are products used in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health. A product becomes a medical device when it is intended for that use. A medical device is considered a new device if substantially equivalent products were not in commercial distribution, prior to May 28, 1976, for the same intended use. New medical devices used in investigations that "present a potential for serious risk to the health, safety, or welfare of a subject" are called "significant risk." Investigations are any clinical trials exposing human subjects to determine the safety or effectiveness of a medical device.

Criteria:

FDA believes that devices used in investigations involving laser products that are Class IV according to the laser standard would present a potential for serious harm and in general must be considered significant risk devices. So also, higher power Class III laser products could be expected to satisfy this criterion, depending on emission level, wavelength, and medical application and may be considered significant risk devices. This does not imply that other laser products are never significant risk devices. After due consideration of the details of the investigation, (e.g., the controls, the patient characteristics, the qualifications of the operator, etc.), an IRB or the FDA may find any investigation to involve significant risk.

Requirement:

Sponsors of investigations using new medical devices that incorporate a Class IV laser product must comply with all of the requirements of 21 CFR 812 applicable to significant risk devices. If a sponsor or manufacturer believes that circumstances indicate that the investigation should not be considered significant risk, the sponsor is urged to write to the Director, Division of Compliance (HFX-400), Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20857, and provide a justification that includes supporting technical data. Sponsors of investigations of new medical devices that use Class III laser products should obtain a determination from the Director, Division of Compliance, whether the FDA considers the investigation to involve significant risk.

Manufacturers, importers and exporters of investigational devices are further advised to consult the regulations of 21 CFR 812, that contain requirements pertaining to the labeling, promotion, and commercialization of such devices.

Sponsors of investigations may contact the IDE Coordinator of the Bureau of Radiological Health (HFX-460), telephone (301) 443-3426, for assistance in developing their IDE submission or in interpreting the IDE regulation.

Sincerely yours,

Walter E. Gundaker
Acting Director
Division of Compliance
Bureau of Radiological Health

U.S. DEPARTMENT OF
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Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20857

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