DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 19 1994

TO: ALL MANUFACTURERS AND POTENTIAL MANUFACTURERS OF MEDICAL LASER PRODUCTS

SUBJECT: Performance Requirements for Medical Laser Products Incorporating Visible Laser Aiming Beams

BACKGROUND: Some medical laser products incorporate a separate lower power laser to provide a visible beam for aiming the higher power medical/surgical laser beam (usually an invisible laser beam). The aiming beam has no direct diagnostic, surgical or therapeutic purpose. The National Center for Devices and Radiological Health has been asked for relief from the measurement requirement (21 CFR 1040.11(a)(1)) for the aiming beam in cases where the aiming beam may exceed the accessible emission limits of Class II. Since aiming beam lasers generally have low power (5mW or less) and fixed output, the incorporation of a means for measurement of the aiming beam level would serve little or no useful purpose.

DISCUSSION: NCDRH has evaluated this proposal and agrees that measurement of the level of a low-power, fixed output aiming beam would be of little benefit since 1) the output power of the aiming beam can not be varied; 2) if the output changes, it would be expected to decrease rather than increase; and 3) a significant decrease in output power of the aiming beam would be readily seen by the user since visibility would be adversely affected. Therefore, granting the requested relief will not compromise the public health and safety.

POLICY: When a medical laser product incorporates an aiming beam laser, the Food and Drug Administration will not object if the incorporated aiming beam laser does not meet the requirements of 21 CFR 1040.11(a)(1) for a means of measuring the level of the aiming beam, provided that the aiming beam laser:

1. Is Class III b with fixed output power not exceeding 5mW;

2. Emits only visible (400 to 710nm) laser radiation in excess of the limits of Class I;

3. Is used solely for aiming purposes; and

4. Is not employed in ocular procedures.

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INVITATION TO COMMENT: The National Center for Devices and Radiological Health intends to propose an amendment to the Federal performance standard for laser products which will clearly permit performance under the conditions specified above. In the meantime, the Food and Drug Administration will not take action under Section 359, 360B, or 360C of the Radiation Control for Health and Safety Act of 1968 if certified laser products deviate from the requirements of 21 CFR 1040.11(a)(1) for aiming beams provided the above conditions are met, since such deviation, while technically noncompliant with the present performance standard, does not compromise the public health and safety. Comments on this policy are invited.

Sincerely yours,

John C. Villforth
Director
National Center for Devices
and Radiological Health