

2/26/99

K990014

510(K) SUMMARY
DIOSCAN SCANNING HANDPIECE ACCESSORY

This 510(k) summary of safety and effectiveness for the handpiece accessory is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Diomed, Inc.
Address: 30-31 Union Wharf
Boston, MA 02109
Contact Person: Adrian Grundy
General Manager
Telephone: 617-723-6593
617-723-6598 (fax)

Preparation Date: December, 1998
(of the Summary)

Device Name: DioScan Scanning Handpiece Accessory

Common Name: Laser Handpiece Delivery System

Classification Name: Accessory to a laser surgical instrument for use in general and plastic surgery and in dermatology
(see: 21 CFR 878.4810). Product Code: GEX. Panel: 79.

Legally marketed predicate device: Lihtan Technologies, Inc. Hexascan Handpiece
Cool Laser Optics, Inc. CLO Contact Cooling System

Description of the Device: The DioScan Scanning Handpiece is intended to allow the rapid treatment of a large area of skin by scanning a laser spot over a treatment area. The area treated allows the majority of the operator's time to be spent in treatment, with a small proportion of time spent in moving the scanner between areas. To minimize patient discomfort and reduce the risk of damage to the dermis, the handpiece employs a cooled sapphire window in thermal contact with the skin during treatment.

Indications for use: The DioScan Scanning Handpiece Accessory is indicated for incision, excision, vaporization, ablation, cutting, hemostasis, and coagulation of soft tissue in dermatology and plastic surgery, including aesthetic surgery.

Comparison to: The specifications of the DioScan Scanning Handpiece Accessory are the same or very similar to those of the claimed predicates.

Performance Data: None. The specifications and indications for use of the DioScan Scanning Handpiece Accessory are the same or very similar to those of the claimed predicate devices. The DioScan Scanning Handpiece Accessory has similar indications for use for which the claimed predicates have been cleared.

Because of this, performance data were not required.

Conclusion: Based on the foregoing, Diomed believes that the DioScan Scanning Handpiece Accessory is substantially equivalent to legally marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 1999

Mr. Adrian Grundy
General Manager
Diomed, Inc.
30-31 Union Wharf
Boston, Massachusetts 02109

Re: K990014
Trade Name: DioScan Scanning Handpiece Accessory
Regulatory Class: II
Product Code: GEX
Dated: December 30, 1998
Received: January 4, 1999

Dear Mr. Grundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

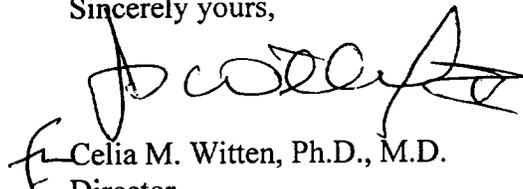
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Adrian Grundy

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K 990014

Device Name: DioScan Scanning Handpiece Accessory

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use
(Per 21 CFR 810.109)

Over-The-Counter Use



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990014³⁶