APR 14 K990417

APPENDIX VII

510(k) summary of Safety and Effectiveness

Submitter: OptoMed, Inc.
13091 Pond Springs Road
Austin, TX 78729

I. Classification: Class II

II. Common or usual name: Accessory to laser system

III. Proprietary Name: DermaCool™

IV. Registration No.: 1645461

V. Classification Name: Accessory to laser system, powered, 79GEX, CFR 878-4810, Class II.

VI. Performance standards: None established (as a medical device) under section 514.

VII. Description: DermaCool™ is a skin-cooling device designed for lasers or light sources, which are used for skin treatment applications such as vascular lesions or hair removal. A piece of cooled sapphire window, or lens, which comes in contact with skin, performs skin cooling.

VIII. Labels and Labeling: Labels and Instructions for Use are provided. Competitive labels and labeling are provided and the products are compared.

IX. Indications for Use: DermaCool™ is intended for use with a laser or light source utilized for photo-coagulation of dermatological lesions and is a cooling device indicated for:

1. The reduction of pain,
2. Less discomfort,
3. Cooling of the skin prior, during and after laser or light treatment.

X. Substantial Equivalence: The DermaCoolTM is substanially equilvalent to laser accessories cleared by Candela under K974381 as a laser accessory, and under K951033 as a pack, hot or cold. It is also equivalent to Cool Laser Optics, Inc. CLO Cool Wand, Cool Bag, and CLO Recirculating Slim Pack which do not appear to have 510(k) clearance.

The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1999

Shahriar Ghaffari, Ph.D.
President
OptoMed, Inc.
13091 Pond Spring Road
Austin, Texas 78729

Re: K990417
Trade Name: DermaCool™ System and Handpiece
Regulatory Class: II
Product Code: GEX
Dated: February 3, 1999
Received: February 10, 1999

Dear Dr. Ghaffari:

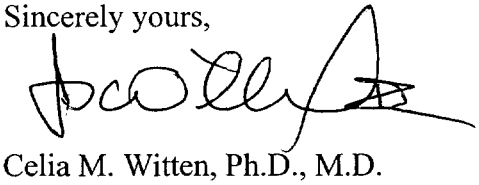
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



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): 990417

Device Name: DermaCool System and Handpieces

Indications For Use: DermaCool is intended for use with a laser or light source utilized for photo-coagulation of dermatological lesions and is a cooling device indicated for:

1. The reduction of pain,
2. Less discomfort,
3. Cooling of the skin prior, during and after laser or light treatment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990417

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)