

K99229P

DEC - 9 1999

**510(k) Summary
IRIDEX Corporation
IRIDERM Apex 800**

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Bradley J. Renton, Ph.D.
IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043
(650) 962-8100

Contact Person: (same as above)

Date Prepared: July 2, 1999

Name of Device and Name/Address of Sponsor

IRIDERM Apex 800

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Classification Name

Laser Instrument, Surgical, Powered
CFR Section: 878.4810
Product Code: 79 GEX

Predicate Devices

The IRIDERM Apex 800 Dermatology Laser System is substantially equivalent to other currently legally marketed dermatology laser devices including the Cynosure, Inc., PhotoGenica LPIR (K971737) and the Coherent, Inc., LightSheer (K973324).

Device Description

The IRIDERM Apex 800 is a semiconductor diode laser system that delivers pulsed infrared 800 nm laser light intended to be used for the indication of hair removal. Energy is delivered into treatment spots of 7 mm, 8.5 mm or 10 mm diameter. The Pulse Duration can be selected from 5 to 30 msec. The maximum Energy Density that can be delivered is dependent on the diameter of the treatment spot and is 40, 32 and 23 J/cm² for spot sizes of 7, 8.5 and 10 mm respectively. Visible red (630-650 nm) semiconductor diode lasers are used for aiming.

Intended Use

The IRIDERM Apex 800 is indicated for hair removal.

Technological Characteristics and Substantial Equivalence

The IRIDERM Apex 800 is substantially equivalent to other currently legally marketed dermatology laser devices including the Cynosure, Inc., PhotoGenica LPIR (K971737) and the Coherent, Inc., LightSheer (K973324). These predicate devices are indicated for hair removal.

The IRIDERM Apex 800 is a semiconductor diode laser system that delivers infrared 800 nm laser light intended to be used for the indication of hair removal. Energy is delivered into treatment spots of 7 mm, 8.5 mm or 10 mm diameter. The Pulse Duration can be selected from 5 to 30 msec. The maximum Energy Density that can be delivered is dependent on the diameter of the treatment spot and is 40, 32 and 23 J/cm² for spot sizes of 7, 8.5 and 10 mm respectively.

The Cynosure, Inc., PhotoGenica LPIR (K971737) delivers pulsed infrared 755 nm laser light intended to be used for the indication of hair removal. Energy is delivered into treatment spots of 7 mm or 10 mm diameter. The Pulse Duration can be selected from 5 to 20 msec. The maximum Energy Density that can be delivered is dependent on the diameter of the treatment spot and is 40 and 25 J/cm² for spot sizes of 7 and 10 mm respectively.

The Coherent, Inc., LightSheer (K973324) is a semiconductor diode laser system that delivers pulsed infrared 800 nm laser light intended to be used for the indication of hair removal. Energy is delivered into a 9 mm square treatment spot. The Pulse Duration can be selected from 5 to 30 msec. The maximum Energy Density that can be delivered is 40 J/cm².

Non-Clinical performance Data: None

Clinical performance Data: None

Conclusion

The IRIDERM Apex 800 is substantially equivalent to predicate devices currently legally marketed for the indication of hair removal.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC - 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bradley J. Renton, Ph.D.
Vice President, Dermatology
IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, California 94043

Re: K992298
Trade Name: IRIDERM Apex 800
Regulatory Class: II
Product Code: GEX
Dated: September 29, 1999
Received: September 30, 1999

Dear Dr. Renton :

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.

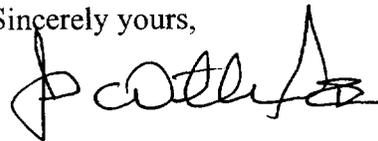
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 – Bradley J. Renton, Ph.D.

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 "J. Dillard III". The signature is fluid and cursive, with a large initial "J" and a prominent "D".

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K992298

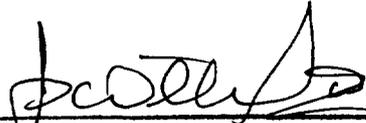
Device Name: IRIDERM Apex 800

Indications For Use:

The IRIDERM Apex 800 is indicated for hair removal.

(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 K992298

Prescription Use

OR
(Per 21 CFR 801.109)

Over-The-Counter Use