K060905

Section 5 – 510(k) Summary or 510(k) Statement

MAY 3 1 2006

I. General Information

Submitter:	IRIDEX Corporation 1212 Terra Bella Avenue Mountain View, CA 94043-1824 USA
Contact Person:	John Jossy Director of Regulatory Affairs and Quality Assurance
Summary Preparation Date:	March 31, 2006

II. Names

Device Names:	IRIDEX OtoProbe
Primary Classification Names:	Accessory for, Laser Powered Surgical Instruments

III. Predicate Devices

- Lumenis EndoOto Probe (K990174)
- CeramOptec MegaBeam Fiber Optic Delivery System (K943445 & 980389)
- Biolitec Megabeam Endo-ENT Probe (K952772)

IV. Product Description

The IRIDEX OtoProbe is comprised of the following main components:

- A glass fiber optic protected by a medical grade stainless steel needle and handle at the distal (patient) end and by a plastic jacket at the proximal (laser connection) end; and
- A universal SMA laser connector.

The IRIDEX OtoProbe is provided as a sterile, single use laser energy delivery system device (accessory). The universal SMA connector at the proximal end of the optical fiber delivery device is designed to be attached to the optical fiber Laser Port of the IRIDEX OcuLight laser system or other 532 nm laser system with universal SMA compatibility that has been qualified by IRIDEX for use with the IRIDEX OtoProbe.

V. Indications for Use

The IRIDEX OtoProbe is intended for use in surgical procedures for use in incision, excision, coagulation, and vaporization of soft and fibrous tissue including osseous tissue in the medical specialty of ENT surgery. The IRIDEX OtoProbe is cleared for use for the particular indications of the compatible laser system to which it is attached.

VI. Rationale for Substantial Equivalence

The IRIDEX OtoProbe shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the IRIDEX OtoProbe is substantially equivalent to the predicate devices.

VIII. Conclusion

The IRIDEX OtoProbe was found to be substantially equivalent to the predicate devices.

The IRIDEX OtoProbe shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2006

IRIDEX Corporation
% Mr. John Jossy
Director of Regulatory Affairs and
Quality Assurance
1212 Terra Bella Avenue
Mountain View, California 94043-1824

Re: K060905
Trade/Device Name: IRIDEX OtoProbe
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 31, 2006
Received: April 5, 2006

Dear Mr. Jossy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060905

Device Name: IRIDEX OtoProbe

Indications for Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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, and Neurological Devices

510(k) Number K060905