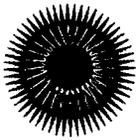


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# Innovatech SURGICAL, INC.

August 25, 2003

## Premarket Notification [510(k)] Summary

**Submitter:** Innovatech Surgical Inc.  
1000 Atlantic Avenue, Suite 514  
Camden, NJ 08104  
Phone: 800-240-3123  
Fax: 856-225-1203

**Official Correspondent:** Michael J. McGowan, Sr.

**Trade Name** Innovatech Straight Laser Probe

**Common Name:** Ophthalmic Laser Probe

**Registration Number:** 3003988504

**Classification:** Class II

**Class Name:** We were unable to find the device listed in the Disposable classification regulations, 21 CFR Parts 862-892 [807.87 (c)]

**Panel:** Ophthalmic

**Product Code:** GEX, HQF

**Device Description:** The Innovatech Straight Laser Probe is an ophthalmic laser delivery device. By its design, it does not generate, intensify or significantly reduce energy. It consists of a connector that is plugged into an existing laser source, a glass fiber with PVC jacket, a Delrin handpiece and a 304 stainless needle. The specific laser source to which the probe is connected will be specified in the "Indications for Use."

**Statement of indications for use:** For photocoagulation during ophthalmic surgery. To be used with (specified equipment).

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1000 Atlantic Avenue, Suite 514, Camden, New Jersey 08104  
800-240-3123  
innovatechsurgical.com

**Substantial Equivalence Comparison**

Application for 510(k)	Substantial Equivalence to:		
<b>Innovatech Straight Laser Probe</b> Product: 420-10	Peregrine Straight Laser Probe Product: PD600.00 Manufactured by Peregrine Surgical Ltd 510(k): K024061	Endo Ocular Laser Probe (Gamp & Associates) 510(k): K954307	Endo Illuminator 25ga. Manufactured by Peregrine Surgical Ltd Familed under 510(k): K980797
Light transmission for photocoagulation	Light transmission for photocoagulation	Light transmission for photocoagulation	Light transmission for illumination
Aluminum connector	Aluminum connector	Aluminum connector	Delrin connector
Delrin Handpiece	Delrin Handpiece	Delrin Handpiece	Delrin Handpiece
Optical Fiber Glass – Silica Core .008" (200 microns)	Optical Fiber Glass – Silica Core .008" (200 microns)	Optical Fiber Glass – Silica Core .008" (200 microns)	Optical Fiber Glass – Silica Core 400 micron
PVC Jacket	PVC Jacket	Teflon Jacket	Teflon Jacket
Length 101 inches	Length 101 inches	Length 96 inches	Length 81 inches
304 Stainless Needle	304 Stainless Needle	304 Stainless Needle	304 Stainless Needle
20 Gauge	20 Gauge	20 Gauge	25 Gauge
Max power output 1 watt	Max power output 1 watt	Max power output 1 watt	N/A

**Sterility**

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is AAMI Overkill Method.



OCT 24 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Michael J. McGowan, Sr.  
Innovatech Surgical, Inc.  
1000 Atlantic Avenue, Suite 514  
Camden, New Jersey 08104

Re: K032703

Trade/Device Name: Innovatech Straight Laser Probe  
Regulation Number: 21 CFR 878.4810, 886.4390  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology, Ophthalmic laser  
Regulatory Class: II  
Product Code: GEX, HQF  
Dated: August 25, 2003  
Received: September 2, 2003

Dear Mr. McGowan:

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.

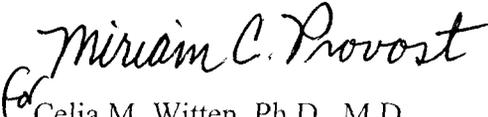
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 - Mr. Michael J. McGowan, Sr.

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 (301) 594-4659. 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,

A handwritten signature in black ink that reads "Miriam C. Provost". The signature is written in a cursive style. To the left of the signature, there is a small handwritten "for" in blue ink.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K032703

Device Name: Innovatech Straight Laser Probe

Indications for Use: For photocoagulation during ophthalmic surgery. This device delivers laser energy to target tissue, causing coagulation. Spot size can be varied by altering the distance between the tissue and the probe tip.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use xx OR Over-The-Counter Use \_\_\_\_\_

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K032703