

3/30/99

K 990851

510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the modified Índigo Diffuser-Tip™ Fiberoptic with Temperature Sensing Option.

Submitter: Índigo Medical, Inc.
10123 Alliance Road
Cincinnati, Oh 45242
Telephone : 513-786-7987
Fax : 513- 483-3410

Contact Person : Jacquelyn A. Hughes, RAC

Device Name :

Trade Name: Índigo Diffuser-Tip™ Fiberoptic with Temperature Sensing Option
Common Name: Diode laser fiberoptic delivery system
Proprietary Name: Índigo LaserOptic™ Treatment System
Classification Name: Accessory to laser-powered surgical instrument

Date Prepared: March 2, 1999

Predicate Device: The modified Índigo Diffuser-Tip™ Fiberoptic with Temperature Sensing Option is substantially equivalent to the current Índigo Diffuser-Tip™ Fiberoptic with Temperature Sensing Option cleared by FDA on December 23, 1997 (K963969).

Device Description: The Índigo Diffuser- Tip™ Fiberoptic is a sterile, single-use, disposable fiberoptic which is 3 meters in length with a light-diffusing section at the distal tip. The device is designed to deliver energy from the Índigo Model 830e diode laser only and bears a unique connector for coupling to the 830e laser at the proximal end. Modifications have been made to increase the resistance to breakage of the fiberoptic and improve the manufacturability of the device. None of the changes affect the function, intended use, or overall design of the fiberoptic or of the Índigo LaserOptic™ Treatment System.

Intended Use: The Índigo 830e LaserOptic™ Treatment System is intended to be used in the contact mode to photocoagulate, vaporize/ablate soft tissue (muscle, connective tissue, organ), and in the contact or non-contact mode for cutting, excision, incision, and coagulation of soft tissue in both open or closed surgical procedures.

Indications

The Índigo 830e LaserOptic™ Treatment System with Diffuser-Tip™ Fiberoptic is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 20-85 cc and for general surgery, general urological and gastroenterological procedures including the incision, excision, and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissues.

Comparison of Technological Characteristics: The technical and functional characteristics of the modified Diffuser-Tip™ Fiberoptic are essentially identical to the existing Diffuser-Tip™ Fiberoptic. The modifications to the components incorporated in the design are refinements to the manufacturing process and to the design which do not represent technological changes. The laser source is the Model 830e diode laser in both cases and the output and resulting lesion size have not changed.

Nonclinical Tests: Testing was performed in order to compare the modified Diffuser-Tip™ Fiberoptic with the existing fiberoptic for equivalence of the tissue temperature profiles and the resulting lesion size. The lesion size, temperature accuracy, internal heating of the fiber, time to reach operating temperature, fiber intensity profile, and total energy delivered were measured and compared. The results indicated that the modified Diffuser-Tip™ Fiberoptic had an equivalent tissue temperature profile, and that the lesion size created by the modified fiberoptic is equivalent to the lesion size created by the current Diffuser-Tip™ Fiberoptic. A reliability assessment was conducted to evaluate the robustness and resistance to breakage of the modified fiberoptic as compared to the current Diffuser-Tip™ Fiberoptic. Results indicated a significant improvement.



MAR 30 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jacquelyn A. Hughes, RAC
Manager, Regulatory Affairs
Indigo Medical, Inc.
10123 Alliance Road
Cincinnati, Ohio 45242

Re: K990851
Trade Name: Indigo Diffuser-Tip™ Fiberoptic with
Temperature Sensing Option
Regulatory Class: II
Product Code: GEX
Dated: March 12, 1999
Received: March 15, 1999

Dear Ms. Hughes:

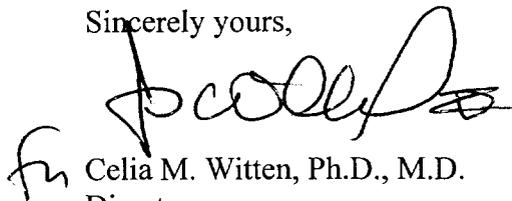
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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

fm 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

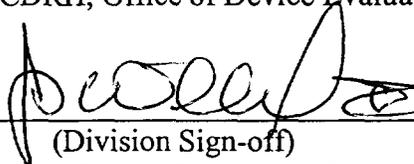
INDICATIONS FOR USE STATEMENT

510 (k) Number (if known) : K990851

Device Name : **Índigo Diffuser-Tip™ Fiberoptic , accessory to the Índigo LaserOptic™ Treatment System**

Indications for Use : **The Índigo LaserOptic™ Treatment System with Diffuser-Tip™ Fiberoptic is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 20-85cc and for general surgery, general urological and gastroenterological procedures including the incision, excision, and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissues.**

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-off)

Division of General Restorative Devices

510(k) number K990851

Prescription Use OR Over-the-Counter Use
(Per 21 CFR 801.109)