K963969

Section K : Summary of Safety and Effectiveness

DEC 23 1997

Invitro and human clinical testing were conducted to establish the equivalence to predicate devices in terms of safety and efficacy and to characterize the performance of the laser system with different types of fiber optics.

When used as a general surgical instrument, the laser is able to provide power to cut or coagulate tissues. The table below shows the penetration depth in porcine tissues (invitro) as a function of time and exposure to diode laser power.

Exposure	Penetration Depth (mm)		
Power/Time	Liver	Kidney	Heart
5 Watts / 1 sec	1.73±0.20	1.75±0.34	1.77±0.37
5 Watts / 2 sec	2.48±0.73	2.29±0.31	2.19±0.62
5 Watts / 5 sec	3.37±0.64	3.31±0.39	3.03±0.72
10 Watts / 1 sec	2.26±0.47	1.90±0.35	2.25±0.62
10 Watts / 2 sec	3.30±0.59	2.36±0.27	2.16±0.35
10 Watts / 5 sec	4.34±0.78	3.65±0.54	2.89±0.34
15 Watts / 1 sec	2.35±0.45	2.60±0.35	2.16±0.32
15 Watts / 2 sec	3.61±0.50	3.17±0.38	2.58±0.34
20 Watts / 1 sec	2.99±0.48	2.64±0.50	1.99±0.36
20 Watts / 2 sec	3.27±1.34	2.98±0.77	3.48±0.79
25 Watts / 1 sec	2.81±1.13	2.24±0.53	2.96±0.83
25 Watts / 2 sec	3.65±0.72	3.17±1.04	2.81±0.44

When used as a coagulating device, the Índigo laser in conjunction with a diffusing fiberoptic provides interstitial laser coagulation. The process of interstitial laser coagulation relies on quickly elevating tissue to a temperature range (Appox. 60 to 100°C) where tissue necrosis rapidly occurs, but below temperatures at which carbonization begins. Lesion sizes vary according to diffuser length and variation of tissue conditions.

The results of a prospective, randomized study shows that the Índigo procedure is safe and effective for the treatment of Benign Prostate Hyperplasia.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sharon Starowicz
Director of Regulatory, Clinical and Quality Systems
Indigo Medical, Incorporated
10123 Alliance Road
Cincinnati, Ohio 45242

DEC 23 1997

Re: K963969
Trade Name: Indigo 830e LaserOptic Treatment System with Diffuser-Tip™ Fiberoptic
Regulatory Class: II
Product Code: GEX
Dated: September 29, 1997
Received: September 30, 1997

Dear Ms. Starowicz:

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.

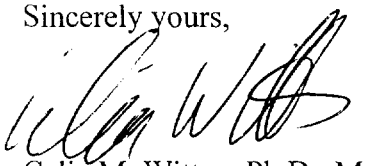
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , 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

INDICATIONS FOR USE

510(k) Number: **K963969**

Device Name: **Indigo 830e LaserOptic Treatment System with Diffuser-Tip™ Fiberoptic**

Indications for Use:

Note: Indigo is requesting the expansion of the indications for use which have already been cleared under K955798 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.

The expanded Indications for Use will read as follows:

The Indigo 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K963969

Prescription Use ✓ **OR** **Over-the-Counter Use**

(Per 21 CFR 801.109) **(Optional Format 1-2-96)**