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**510(k) SUMMARY**


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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 Índigo Prostate Seeding Needle Cartridge System.

**Submitter:**

Índigo Medical, Inc.  
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 Cincinnati, Oh 45242  
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**Contact Person :**

Jacquelyn A. Hughes, RAC

**Device Name :**

Trade Name:	Índigo Prostate Seeding Needle Cartridge System
Common Name:	Accessory to applicator and accessory to radionuclide brachytherapy source
Proprietary Name:	Índigo Prostate Seeding Needle Cartridge System
Classification Name:	System, applicator, radionuclide, manual & Source, brachytherapy, radionuclide (accessory to)

**Date Prepared:**

June 30, 1999

**Predicate Device:** The predicate device to the Índigo Prostate Seeding Needle Cartridge is the Mick seed magazine used in conjunction with the Mick <sup>TM</sup> 200-TP Applicator cleared under 510(k) K890341. The predicate devices to the Índigo Seed Spacer are I-125 Rapid Strand<sup>TM</sup>, cleared under K940632, and LOOK, Inc. Spacing Material, 510(k) number unknown.

**Device Description:** The Índigo Prostate Seeding Needle Cartridge System consists of two main components, a single use, disposable seed magazine with a stainless steel shield and a Polyglactin 910 (PG910) absorbable spacer, which is a small cylindrical pellet utilized to provide space between the radionuclide seeds as they are implanted into the body. Both devices are intended to be used **only** in conjunction with Índigo Prostate Seeding Needles.

**Intended Use:** The Índigo Prostate Seeding Needle Cartridge System is a single use, disposable system which is intended as a convenience and radiation safety device for the purpose of loading a radionuclide brachytherapy source into the Índigo Prostate Seeding Needles for prostate brachytherapy.

**Indications:** The Índigo Prostate Seeding Needle Cartridge System is indicated for use in conjunction with the Índigo Prostate Seeding Needle to deliver a radionuclide brachytherapy source for permanent interstitial implantation in the prostate gland for the treatment of localized tumors which are of low to moderate radiosensitivity.

**Comparison of Technological Characteristics:** The Índigo Prostate Seeding Needle Cartridge is a single use, disposable device for delivering radionuclides into a manual applicator preoperatively while the Mick magazines are reusable and single use, disposable devices for delivering radionuclides into a manual applicator intraoperatively.

The Índigo Seed Spacer is an absorbable pellet of PG 910 intended to maintain 1 cm spacing between seeds of either I-125 or Pd-103 when delivered by a preloaded seeding needle into the prostate. The I-125 Rapid Strand™ is a device of braided, absorbable VICRYL® Suture imbedded with I-125 seeds at 1 cm intervals center to center for delivery by preloaded seeding needle into the prostate.

**Nonclinical Tests:** Functional testing of the cartridge material and compression testing of the spacers were performed post-autoclaving to ensure the durability and functionality of the devices. A time study and radiation scanning were done to ensure that the cartridge system reduces the physicist's barriers (time and radiation exposure) for the preloaded seed delivery technique.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 4 1999

Jacquelyn A. Hughes  
Regulatory Affairs Manager  
Indigo Medical Inc.  
10123 Alliance Road  
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Re: K992262  
Indigo Prostate Seeding Needle Cartridge System  
Dated: July 2, 1999  
Received: July 6, 1999  
Regulatory class: II  
21 CFR 892.5730/Procode: 90 KXX

Dear Ms. Hughes:

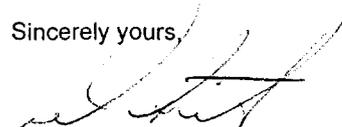
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,



Capt. Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

510 (k) Number (if known): K992262

Device Name : Indigo Prostate Seeding Needle Cartridge System

Indications for Use : The Indigo Prostate Seeding Needle Cartridge System is indicated for use in conjunction with the Indigo Prostate Seeding Needle to deliver a radionuclide brachytherapy source for permanent interstitial implantation in the prostate gland for the treatment of localized tumors which are of low to moderate radiosensitivity.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson  
(Division Sign-off)

Division of Reproductive, Abdominal, ENT & Radiological Devices

510(k) number K992262

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-the-Counter Use