K01 0166

DEC 0 3 2001

510(k) Summary

Sponsor:	Imagyn Medical Technologies, Inc. 8850 M-89 Richland, MI 49083 (616) 629 2787 Contact: Julie Powell
Summary Preparation:	May 1, 2001
Device:	Imagyn isosleeve™/isostar™ Needle System
Predicate Devices:	Medi-Physics, Inc. I-125 Rapid Strand™ Mick Applicator & Magazine
Device Description:	The Imagyn isosleeve™/isostar™ Model ISS-12501 Needle System is a preloaded, pre-sterilized, and pre-assayed brachytherapy seed dispensing system. The system consists of the Imagyn isosleeve, Imagyn isostar I-125 Interstitial Brachytherapy Seeds (K991526), spacers (K001299), and a standard 18 gauge needles with blunt-tip obturator (K902622). All the components of this system, with the exception of the Imagyn isosleeve, have previously received 510(k) clearance.
Indication for Use:	The Imagyn isosleeve/isostar Needle System is indicated for delivery of isostar Iodine 125 Interstitial Brachytherapy Seeds and spacers during implantation of radioactive seeds in selected localized prostate tumors.
Technological Comparisons and Substantial Equivalence:	The Imagyn isosleeve/isostar Needle System is substantially equivalent to the Medi-Physics 1-125 Rapid Strand. Both devices are preloaded per physician's treatment plan and provided sterile and ready to use. The major difference between these devices is that the Rapid Strand has the I-125 Brachytherapy Seeds encapsulated in braided suture material, while the isosleeve/isostar system contains individual 1-125 Brachytherapy Seeds and spacers preloaded into needles, which are dispensed from the isosleeve into selected tumors.. The Imagyn isosleeve/isostar Needle System is also equivalent in terms of actual final use to the Mick Applicator & Magazine, although this device is not provided sterile. The Imagyn isosleeve/isostar Needle System and predicate devices are all utilized by physicians for permanent interstitial implantation of radioactive brachytherapy seeds during prostate surgeries

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2001

Ms. Julie Powell
Vice President Quality Assurance
and Regulatory Affairs
Imagyn Medical Technologies
3100 Jim Christal Road
DENTON TX 76207-2600

Re: K010166
Trade/Device Name: Imagyn Isosleeve™/Isostar™ Needle System
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Regulation Number: 21 CFR 892.5650
Regulation Name: Manual radionuclide applicator system
Regulatory Class: I
Product Code: 90 IWJ
Dated: September 11, 2001
Received: September 17, 2001

Dear Ms. Powell:

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 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4629. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

INDICATIONS FOR USE

510(k) Number (if known): K010166

Device Name: Imagyn isosleeve™ / isostar™ Needle System

Indications for Use:

The Imagyn isosleeve / isostar Needle System is indicated for the delivery of isostar Iodine 125 Interstitial Brachytherapy Seeds and spacers during implantation of radioactive seeds in selected localized prostate tumors.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-the-Counter Use_____

Nancy C. Brogdon

(Division Sign-Off)
Division of [redacted]
and [redacted]
510(k) Number K010166