K030594

APR 10 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following 510(k) Summary of Safety and Effectiveness is prepared and provided in accordance with the requirements of 21 CFR 807.92 as amended under the Safe Medical Devices Act of 1990 (SMDA).

Submitter's Information

Company Name:	Medi-Physics, Inc DBA Amersham Health
Address:	101 Carnegie Center Princeton, NJ 08540-6231
Contact Name:	Subhash Patel Associate Director, Regulatory Affairs
Telephone Number:	(609) 514-6846
Summary Prepared Date:	February 19, 2003

Subject Device Information

Trade Name:	RAPID Strand™	Model: 7000
Common Name:	Radionuclide Brachytherapy Source	
Class:	II	
Classification:	21 CFR 892.5730	Product Code: 90-IWI

Predicate Devices Legally marketed devices to which equivalence is claimed.

1.

Trade Name:	RAPID Strand™	Model: 7000
Common Name:	Radionuclide Brachytherapy Source	
Class:	II	
Classification:	21 CFR 892.5730	Product Code: 90-IWI
Cleared 510(k) No.:	**K940632**	
Submitted by:	Medi-Physics, Inc., Arlington Heights, IL	

2.

Trade Name:	OncoSeed™	Model: 6711
Common Name:	Radionuclide Brachytherapy Source	
Class:	II	
Classification:	21 CFR 892.5730	Product Code: 90-KXK
Cleared 510(k) No.:	**K914281**	
Submitted by:	Medi-Physics, Inc., Arlington Heights, IL	

3.

Trade Name:	Coated VICRYL (Polyglactin 910) Synthetic Absorbable Suture
Common Name:	Absorbable Poly (glycolide/L-lactide) surgical suture
Class:	II
Classification:	21 CFR 892.4493 Product Code: GAM
Cleared 510(k) No.:	**K022269** (September 13, 2002)
Submitted by:	Ethicon, Inc., Somerville, NJ

K03 0594

4. Trade Name: Absorbable Seeding Spacers
Common Name: Accessory to applicator and accessory to radionuclide Brachytherapy Sources
Class: II
Classification: 21 CFR 892.5730 Product Code: 90 KXK
Cleared 510(k) No.: **K013964** (January 24, 2002)
Submitted by: CP Medical, Portland, OR

Description of Device

RAPID Strand™ consists of 11 absorbable seeding spacers and 10 Model 6711 OncoSeed™ seeds (welded titanium capsule containing I-125 adsorbed onto a silver rod) spaced at a fixed distance within absorbable braided carrier. The absorbable braided carrier containing OncoSeeds and absorbable seeding spacer is stiffened and then sterilized by Ethylene Oxide. The seeds are housed in a plastic spacing jig within a stainless steel shielding tube which attenuates >99% of the I-125 photons. RAPID Strand™ is STERILE when shipped.

The Customized RAPID Strand allows the variable seed spacing to reflect individual patient prescriptions as specified by the treating physician. This Customized RAPID Strand will have less than ten (10) OncoSeed™ seeds and a variable number of Absorbable Seeding Spacers. The treating physician will determine the required dose and total number of active seeds for each Customized RAPID Strand. Since it will contain less than 10 Brachytherapy seeds, it does not raise any issues of safety. Please refer to Seed Spacing Diagram in **Section-E**

Intended Use

RAPID Strand™ consists of absorbable seeding spacers and Model 6711 OncoSeed™ seeds, embedded within Polyglactin 910 Synthetic Absorbable Braided Carrier and is intended for medical purposes to be placed into a body cavity or tissue as a source of nuclear radiation for therapy.

Indications for Use

RAPID Strand ™ is indicated for permanent interstitial implantation of selected localized tumors which are low to moderate radiosensitivity. They may be used either as primary treatment (such as prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor.

RAPID Strand™ may be indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.

When compared with the Intended Use and Indications for Use of the predicate model 7000 RAPID Strand™, the Intended Use and Indications for Use of the subject model 7000 RAPID Strand™ have not changed.

K030594

Technological Characteristics

The following modifications have been incorporated in the subject device - Model 7000 RAPID Strand™ when compared to predicate device:

Modified Characteristics	**7000 RAPID Strand** (Subject Device)	**7000 RAPID Strand** (Predicate Device) Cleared in 510(k)# **K940632**
Absorbable Seeding Spacers		
Regulatory Status	Cleared in 510(k)# K013964	Not applicable
Number of Spacers	11 (Eleven)	None
Base Material	90% Glycolide + 10% L-lactide	None
Color	D&C Violet No.2 (21 CFR 74.3602)	None
Coated VICRYL (Polyglactin 910) Braided Carrier Material		
Regulatory Status	Cleared in 510(k) # K022269	Cleared in 510(k) # K940632
Base Material	Ethicon JB947 – Coated VICRYL (Polyglactin 910) Synthetic Absorbable Suture	Ethicon J617 - Coated VICRYL (Polyglactin 910) Synthetic Absorbable Suture
Formulation	Polyglactin 910 [90% Glycolide + 10% L-lactide coated with Polyglactin 370 and calcium stearate]	Polyglactin 910 [90% Glycolide + 10% L-lactide coated with Polyglactin 370 and calcium stearate]
Appearance	Undyed (Natural)	Coated Vicryl Violet (D&C Violet #2)
Sterilization	Sterile (EtO sterilization performed on finished device)	Sterile (EtO sterilization performed on finished device)

All other technological characteristics of the subject 7000 RAPID Strand™ remain unchanged compared to the predicate RAPID Strand™ that was cleared in the 510(k) # K940632.

Nonclinical Test Data

The copies of the following Nonclinical Test Data reports have been provided in the **Section-G** of this submission.

1. Report of Analysis: Infrared Spectroscopy – FTIR Spectra of the predicate RAPID Strand (finished device) by Northview Laboratories, Inc., Northbrook, IL

2. Report of Analysis: Infrared Spectroscopy – FTIR Spectra of the subject RAPID Strand 1.5 (finished device) by Northview Laboratories, Inc., Northbrook, IL

Conclusion:

Upon reviewing the safety and effectiveness information provided in this submission and comparing the intended use, indications for use, method of use and other technological characteristics, it can be concluded that the subject RAPID Strand™ is substantially equivalent to the predicate RAPID Strand™, which was cleared under 510(k)# K940632.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2003

Mr. Subhash Patel
Associate Director Regulatory Affairs
Amersham Health
101 Carnegie Center
PRINCETON NJ 08540

Re: K030594
Trade/Device Name: I-125 RAPID Strand
Model 7000
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: March 25, 2003
Received: March 27, 2003

Dear Mr. Patel:

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 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 our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. 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

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

Enclosure

EXHIBIT-2

Indications for Use Form

510(k) Number (if known): K030594

Device Name: Model: 7000 RAPID Strand™

Indications For Use:

RAPID Strand ™ is indicated for permanent interstitial implantation of selected localized tumors which are low to moderate radiosensitivity. They may be used either as primary treatment (such as prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor.

RAPID Strand™ may be indicated for use concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030594

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)