NOV 3 0 2006

K063177

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

Submitter Name:	Subhash Patel, RAC Consultant
Sponsor Name: *Address:*	Oncura Inc. 401 Plymouth Road Plymouth Meeting, PA 19462
Contact Name: *Phone Number:* *E-mail:*	Subhash Patel, RAC (732) 821-7021 spatelraqpro@yahoo.com
Summary Prepared Date:	October 5, 2006

Subject Device Information

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

Predicate Devices Legally marketed device to which equivalence is claimed.

Trade Name:	RAPID Strand™
Model:	7000
Common Name:	Radionuclide Brachytherapy Source
Class:	II
Classification:	21 CFR 892.5730
Product Code:	90-KXK
Cleared in 510(k):	**K030594** and **K940632**
Owner/Holder:	Medi-Physics, Inc., Arlington Heights, IL

Description of Device

RAPID Strand™ Rx is consists of absorbable seeding spacers and radionuclide brachytherapy sources spaced at prescribed distance and configuration within a sleeve (tube) made of absorbable suture material, stiffened, loaded into prostate seeding needles, packaged and then sterilized by Gamma sterilization method. The apparent activity of the seed ranges from 0.191 to 1.01 mCi that correspond air kerma strength value of 0.243 to 1.285 $\mu Gym^2/h$ per seed. RAPID Strand™ RX is sterilized and ready to be use when shipped. RAPID Strand™ Rx should not be re-sterilized.

Intended Use

RAPID Strand™ Rx is a device specifically made in accordance with a medical specialist's written prescription, specified dose and design characteristics. It is intended to be use only for an individual named patient and for medical purposes to be placed onto a body surface or 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.

Technological Characteristics

Section-F of this submission contains comparison of Similar and different characteristics compared to the predicate device (RAPID Strand™). All components used in the subject device have been previously cleared through 510(k) process. The differences shown in the table do not raise any issue about safety or efficacy of the subject device for its intended use. The labeling has been revised for clarity of device use and changes are non-significant. Please refer to Section-G for the Draft Copy of the proposed labeling. Please refer to the Section-C through Section-G for details.

Non-clinical Test Data

Non-clinical test data that includes design validation, process validation, bench test results and sterilization validation have been provided in the Section-H. Based on the results, one can conclude that changes made to the design and manufacturing processes do not raise any question about the safety and efficacy of the subject device for its intended use.

Conclusion:

Upon reviewing the safety and effectiveness information provided in this submission and comparing the design, intended use, indications for use, method of use and other technological characteristics, it can be concluded that the subject RAPID Strand™ Rx is substantially equivalent to the predicate RAPID Strand™ which was cleared under 510(k) # K030594 and K940632.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

ONCURA, Inc.
% Mr. Subhash Patel
RA Consultant
43 Palmetto Way
NORTH BRUNSWICK NJ 08902

NOV 3 0 2006

Re: K063177
Trade/Device Name: RAPID Strand™ Rx
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: October 19, 2006
Received: October 23, 2006

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 (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 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 this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use Form

510(k) Number (if known): K063177

Device Name: RAPID Strand™ Rx

Indications For Use:

RAPID Strand ™ Rx is indicated for permanent interstitial implantation of selected localized tumors, which are low to moderate radio sensitivity. 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™ Rx 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)

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063177