JAN 26 2005

THERAGENICS CORPORATION®

K043596

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510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Device Name:	TheraLoad™ Custom Loaded Needles
Device Model Number:	Model 200 (Pd-103), Model I25.S06 (I-125)
Classification Name:	Radionuclide Brachytherapy Source (KXK), 21 CFR 892.5730
Device Classification:	Class II (Radiology)
Predicate Devices:	TheraSeed, K010283 (2001) I-Seed I-125, K021343 Brachytherapy Strand Device, K040339
Manufacturer:	Theragenics Corporation® 5203 Bristol Industrial Way Buford, GA 30518
Establishment Registration Number:	1037598
Official Contact:	Betsy Cortelloni, Regulatory Affairs Manager Theragenics Corporation 5203 Bristol Industrial Way Buford, GA 30518 Phone: 770-831-4294 Fax: 770-831-4369 cortellb@theragenics.com

Intended Use: TheraLoad™ is a sterile prostate-seeding kit containing TheraSeed® (Pd-103) or I-Seed (I-125) seeds and spacers custom loaded according to the treatment plan.

The brachytherapy source is intended to treat localized, unresectable tumors with low to moderate radiosensitivity. Tumors may be recurrent or residual following external beam or excision of primary tumor and may be superficial, intrathoracic (head, neck, lung), or intra-abdominal (pancreas, prostate).

Device Description: TheraLoad™ is a sterile prostate-seeding kit containing TheraSeed® (Pd-103) or I-Seed (I-125) seeds and bioabsorbable spacers custom loaded according to the treatment plan.

The variable seed spacing available with TheraLoad™ allows the treating medical physicist to specify individual patient prescriptions. The customized order can contain a variable number of seeds and/or spacers (1-12 total components). The treating medical physicist determines the total number of active seeds required for each order.

The spacer material is biocompatible and commonly used in implantable medical devices.

Comparison of Technological Characteristics: TheraLoad™ is functionally equivalent to the predicate TheraStrand™. TheraLoad™ utilizes the same materials, packaging, and methods (manufacturing, inspection, sterilization) TheraStrand™.

Use Type: TheraLoad™ device is custom ordered to an individual patient prescription. TheraLoad™ is provided sterile and is single use device.

Sealed Source Classification: TheraLoad™ can be configured with TheraSeed® (Pd-103) or I-Seed (I-125).

- The Sealed Source Device Registration Number for TheraSeed® is **GA 645S101S,** and the ISO Sealed Sourced Classification for TheraSeed® is **ISO/99/C53211**
- The Sealed Source Device Registration Number for I-Seed is **GA 645S102S,** and the ISO Sealed Sourced Classification for I-Seed is **ISO/99/C63211**

Design Verification: TheraLoad™ was developed in accordance with 21 CFR 820.30 – Design Controls. Design validation and verification testing was conducted to demonstrate compliance with device performance specifications and to establish device safety.

The following standards were used in the development of TheraLoad™ Custom Loaded Needles:

- AAMI TIR 27:2001, Sterilization of Healthcare Products – Radiation Sterilization – Substantiation of 25 kGy as a sterilization dose – Method VD Max
- ANSI/AAMI/ISO 11137:1994, Sterilization of Healthcare Products – Requirements for validation and routine control – Radiation Sterilization
- EN 552:1994, Sterilization of Medical Devices – Validation and routine control of sterilization by irradiation
- ANSI/AAMI/ISO 11737-1-1995, Sterilization of medical devices – Microbiological methods – Part 1: Estimation of population of microorganisms on products
- ANSI/AAMI/ISO 11737-2-1997, Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of sterilization process
- ISO 11607:2003, Packaging for terminally sterilized medical devices
- ASTM F1140-00, Standard Test Methods for internal pressurization failure resistance of unrestrained packages for medical applications
- ASTM F1886-98, Standard Test Method for determining integrity of seals for medical packaging by visual inspection

- ASTM F1929-98, Standard Test Method for detecting seal leaks in porous medical packaging by dye penetration
- ASTM F2096-02 Standard Test Method for detecting gross leaks in medical packaging by internal pressurization (Bubble Test)

Conclusion: The results of the V&V testing confirmed that design inputs were achieved and the cumulative test results demonstrated the functionality, safety and effectiveness of TheraLoad™ Custom Loaded Needles, as well as its substantial equivalence to the predicate TheraStrand™.

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INDICATIONS FOR USE FORM

510(K) number (if known): K043596

Device Name: TheraLoad™ Custom Loaded Needles

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFRR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2005

Ms. Betsy Cortelloni
Regulatory Affairs Manager
Theragenics Corporation
Corporate Offices
5203 Bristol Industrial Way
BUFORD GA 30518

Re: K043596
Trade/Device Name: TheraLoad™ Custom Loaded Needles
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: December 27, 2004
Received: December 29, 2004

Dear Ms. Cortelloni:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (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

INDICATIONS FOR USE FORM

510(K) number (if known): K043596

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFRR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043596