K113210

ISOAID

AUG 10 2012

510 (k) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

IsoAid, LLC
7824 Clark Moody Blvd., Port Richey, FL 34668
Phone: 727-815-3262
Fax: 727-815-1973

Contact Person: Benjamin Roedell

Date of Summary: August 7, 2012

Trade Name: Advantage-Strand™ / Advantage-Load™ Brachytherapy Kit

Common Name: Brachytherapy Seed Strand in Needle

Classification: Class II (21 CFR 892.5730, Product Code KXK)

Classification Name: Radionuclide Brachytherapy Source

Predicate Devices:

Device	510(k) #
Brachytherapy Strand Device	K040339
SeedLinks™	K023210
MacroPore Surgi-Wrap (TS)	K012025

Device Description: The IsoAid Brachytherapy Kit is a pre-sterilized kit containing brachytherapy needle and a custom-loaded strand (K013975 or K103449 or Secure Strand) of seeds spaced at a precise distance within absorbable suture. The strand is optional, when no strand is requested the seeds and spacers are custom-loaded directly into the needle. A maximum total of 20 seeds and spacers can be loaded into a needle. The spacers (K010621 or K103449) are made from the same material as the sutures. The stranded Pd-103 (K033770) and I-125 (K011205) implants are placed inside the needle. Bone Wax (K024372 or Ethicon, Inc. Bone Wax) is used at the tip of the need to keep the implants from falling out. The needle is made from 18-gauge stainless steel.

Intended Use: The IsoAid Brachytherapy Kit is intended for the treatment of selected localized tumors. The devices are implanted as a source of nuclear radiation for therapy.

Indications for Use: The IsoAid Brachytherapy Kit is indicated for tumors that are localized, unresectable, or have low to moderate radiosensitivity.

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Comparison to Predicate Device for Device as a Whole:

	IsoAid Brachytherapy Kit	Bebig Brachytherapy Strand Device
510(k) Number	K091117	K040339
Indications for Use	Same	
Description	The IsoAid Brachytherapy Kit is a pre-sterilized kit containing brachytherapy needle and a custom-loaded strand (K013975) of seeds spaced at a precise distance within absorbable suture. The strand is optional, when no strand is requested the seeds and spacers are custom-loaded directly into the needle. A maximum total of 20 seeds and spacers can be loaded into a needle. The spacers (K010621) are made from the same material as the sutures. The stranded Pd-103 (K033770) and I-125 (K011205) implants are placed inside the needle. Bone Wax (K024372) is used at the tip of the need to keep the implants from falling out. The needle is made from 18-gauge stainless steel.	The Brachytherapy Strand Device is used for the treatment of localized tumors and is placed into a body cavity or tissue. It consists of a pre-sterilized kit containing a prostate seeding needle and a custom-loaded strand of seeds spaced at a precise distance within absorbable suture. The spacers are made from the same material as the sutures. The customized strand can contain a variable number (1-12) of seeds and/or seeding spacers (maximum 12 components per strand). The stranded Pd-103 and I-125 implants are placed inside the needle. The needle is made from 18 gauge stainless steel.
Radioactive Isotope(s)	Iodine-125 and/or Palladium-103	Same
Application Method	Through an 18 gauge needle	Same

Comparison to Predicate Devices for Secure Strand Material:

	IsoAid Brachytherapy Kit	SourceTech SeedLinks™
510(k) Number	K091117	K023210
Indication for Use	The IsoAid Brachytherapy Kit is indicated for tumors that are localized, unresectable, or have low to moderate radiosensitivity.	SeedLinks™ are indicated for use in brachytherapy source spacing and linking in brachytherapy procedures.
Reason for comparison	The Secure Strand used by IsoAid is of the same material as the SourceTech SeedLinks™.	

	IsoAid Brachytherapy Kit	MacroPore Surgi-Wrap (TS)
510(k) Number	K091117	K012025
Compare statements	**Indications for Use:** The IsoAid Brachytherapy Kit is indicated for tumors that are localized, unresectable, or have low to moderate radiosensitivity.	**Design Characteristics:** MacroPore Surgi-Wrap (TS) is a resorbable implant in sheet form manufactured from poly lactic acid (PLA). …
Reason for comparison	The Secure Strand material used by IsoAid is of the same material composition as the MacroPore Surgi-Wrap (TS).	

Standards Used for Bench and Animal Testing in Device Evaluation

ANSI/AAMI/ISO 10993- 10993-1: Evaluation and testing within a risk management process
ANSI/AAMI/ISO 10993- 10993-3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ANSI/AAMI/ISO 10993- 10993-5: Tests for in vitro cytotoxicity
ANSI/AAMI/ISO 10993- 10993-6: Tests for local effects after implantation
ANSI/AAMI/ISO 10993- 10993-7: Ethylene oxide sterilization residuals
ANSI/AAMI/ISO 10993- 10993-10: Tests for irritation and skin sensitization
ANSI/AAMI/ISO 10993- 10993-11: Tests for systemic toxicity
ANSI/AAMI/ISO 10993- 10993-12: Sample preparation and reference materials
ANSI/AAMI/ISO 10993- 10993-13: Identification and quantification of degradation products from polymeric medical devices
ASTM F1635-11 Standard Test Method for In Vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants.

Conclusions:

Based on the results of the bench and animal tests performed it is concluded that these tests demonstrate that the Advantage-Strand™ / Advantage-Load™ Brachytherapy Kit is as safe, as effective, and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Mr. Benjamin Roedell
Quality Assurance Manger
IsoAid, L.L.C.
7824 Clark Moody Boulevard
PORT RICHEY FL 34668

Re: K113210
Trade/Device Name: Advantage-Strand™ /Advantage-Load™ Brachytherapy Kit
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: July 26, 2012
Received: July 27, 2012

Dear Mr. Roedell:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Advantage-Strand™ / Advantage-Load™ Brachytherapy Kit

Indications for Use: The IsoAid Brachytherapy Kit is indicated for tumors that are localized, unreselectable, or have low to moderate radiosensitivity.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
510k k113918 OIVD