MAR 2 9 2006

K051753

510(k) Summary

Submitter: Oncology Systems, Inc.

Address: 206 N. Randolph Street, Suite 300
Champaign, IL 61820

Phone number: (217) 355-4460

Fax number: (217) 355-4470

Contact Person: Jennifer Williams

Date Prepared: May 27, 2005

Trade Name: ACCU-SOURCE™

Common Name: Remote Control High Dose Rate Afterloading Brachytherapy Device

Classification name: Remote Controlled Radionuclide System, 90 JAQ, Regulation 21 CFR §892.5700.

Substantial Equivalence claimed to:

1. Nucletron-Oldeft Corporation **K953946 Microselectron-HDR Version 2**

K051753

Description:

The ACCU-SOURCE™ is a remote afterloading system for High Dose Rate Brachytherapy. The system is designed to deliver a predetermined dose of radiation to organs and tissue via a radioactive source.

The ACCU-SOURCE™ system includes an operator console and a remote afterloading device. The ACCU-SOURCE™ system has a tungsten shielded storage safe which houses a radioactive source when the system is not in use. There are encoders and motors used in conjunction with electronic circuitry that drive the source and keep track of its position. A battery is used for back-up power and an uninterruptible power supply is also integrated into the ACCU-SOURCE™ system to charge the battery backup subsystem.

Intended Use:

The ACCU-SOURCE™ remote controlled high dose rate afterloading brachytherapy system is intended for the treatment of cancer and other lesions by intracavitary, interstitial, intralumenal, intraoperative, endobronchial and surface applicator irradiation treatments.

Technical Specifications:

Comparison Table
Substantial Equivalent Device

The ACCU-SOURCE™ system is comparable to:

- Nucletron MicroSelectron HDR Version 2

FEATURE Device		**Nucletron Micro-Selectron**	**Oncology Systems, Inc. ACCU-SOURCE™**
	Intended Use	Remote Afterloading Brachytherapy unit for interstitial, intracavity, intralumenal, including bronchial, intraoperative, and surface applicator treatments	The ACCU-SOURCE remote control high dose rate brachytherapy system is intended for the treatment of cancer and other lesions by intracavity, interstitial, intralumenal, intraoperative, endobronchial and surface applicator irradiation treatments
	Base Area		
	Height	Variable	101cm
	Weight	150 lbs	180 lbs
	Transportable	V2 only	Yes
	Power Supply	110 VAC	110 VAC/220 VAC
	Mobile	Yes	Yes

K051753

		Nucletron Micro-Selectron	Oncology Systems, Inc. ACCU-SOURCE™
	HDR	Yes	Yes
	Number of Channels	18	24
	Shielding	Tungsten	Tungsten
	Maximum Activity of Shielding	10 Ci	12 Ci
	Maximum Treatment Activity	10 Ci	12 Ci
	Maximum exposure rate a XX distance containing the maximum activity	At 10cm = >2mR/h	Inner vault: > 100mR/h at 20cm Outer vault: >2mR/h at 10cm
	Dwell positions per channel	48	Up to 100 dwell points per channel not to exceed 1200 dwell points (Ex. 24 channels w/ 50 dwell points each or 12 channels w/100 dwell points each)
	Total Channels	18	24
	Contains radiation monitor	Optional	Yes, Included
	Device Control OS Software	Windows	Windows XP
	Treatment Data maintained during power failure	Yes	Yes
	Simulator (Dummy) Source	Yes	Yes
	Verification of Channel Length by direct measurement	Yes By direct measurements	Yes By direct measurements
	Source Positioning	Distal to proximal	Distal to proximal
	Maximum Source Position error over treatment length (+/- .5mm)	1mm	.5 mm
	Emergency container for the source included	Optional	Yes, Included
	Response to Emergency signal	Automatic Retraction of Source	Automatic Retraction of Source
	Emergency manual retraction	Yes	Yes

K051753

		Nucletron Micro-Selectron	Oncology Systems, Inc. ACCU-SOURCE™
Source	Isotope	Ir^{192}	Ir^{192}
	Maximum Activity	10 Ci	12 Ci for Ir^{192}
	Maximum Treatment Activity	10 Ci	12 Ci for Ir^{192}
	Capsule Dimensions	4.5mm length by .9mm width	4.5mm length by .9mm width for Ir^{192} and 6.9 mm length by 1.17 mm width for Yb^{169}
	Active dimensions	3.6mm length by .65mm width	3.6mm length by .65mm width for Ir^{192} and 5.4mm length by .8mm width for Yb^{169}
	Source extension length	150cm	160cm
Operator Console	Operating console with personal computer	Yes	Yes
	Keyswitch Control	Yes	Yes
	Operating Voltage	110/220 VAC	110/220 VAC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Ms. Jennifer Williams
Official Correspondent
Oncology Systems, Inc.
206 N. Randolph Street, Suite 300
CHAMPAIN IL 61820

Re: K051753
Trade/Device Name: ACCU-SOURCE
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: February 16, 2006
Received: February 21, 2006

Dear Ms. Williams:

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/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

510(k) Number (if known): K051753

Device Name: ACCU-SOURCE™

Indications for Use:

The ACCU-SOURCE™ remote control high dose rate afterloading brachytherapy system is indicated for the treatment of cancer and other lesions by intracavitary, interstitial, intralumenal, intraoperative, endobronchial and surface applicator irradiation treatments.

(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 K051753