K092522

ONCOLOGY SYSTEMS

206 N. Randolph Street, Suite 301
Champaign, IL 61820

NOV 20 2009

Section 5
510(k) Summary

Section 807.92(a)

(1) Submitter

Oncology Systems, Inc.
206 N. Randolph Suite 301
Champaign, IL 61820

Tel: 217-355-4460
Fax: 217-355-4470

Establishment Registration No.: SBD096102

Contact Person: Jennifer Williams
FDA Official Regulatory Correspondent
e-mail: jwilliams@oncosys.net

Date Summary Prepared: 03/27/09

(2) Device Name: ACU-007S

Common or Usual Name: Brachytherapy Source Assembly

Classification Name: Source Wire, Iridium Radioactive (21CFR 892.5730;PC;IWA;KXK)

Proprietary Name: Oncology Systems, Inc. Model ACU-007S

(3) Legally Marketed Predicate Devices:

Source Production and Equipment Company Model M-19, 510(k) number K052947 dated 19 April 2006

(4) Description of Oncology Systems, Inc. Model ACU-007S ^{192}Iridium Brachytherapy Source:

Oncology Systems, Inc. Model ACU-007S is a singly-encapsulated ^{192}Iridium Brachytherapy Source. It consists of a single solid radioactive ^{192}Iridium pellet sealed in a stainless steel capsule that is attached to a cable. Its purpose is to permit manipulation by the Oncology Systems, Inc AccuSource 1000 remote afterloader system for the treatment of cancer and other lesions.

(5) Intended Use

The intended use of Oncology Systems, Inc. Model ACU-007S Brachytherapy Source is for the treatment of cancer and other lesions by temporary interstitial, intracavitary, intraluminal, intraoperative or surface irradiation.

ONCOLOGY SYSTEMS

206 N. Randolph Street, Suite 301
Champaign, IL 61820

(6) Technological Characteristics:

Oncology Systems, Inc, Model ACU-007S ^{192}Iridium Brachytherapy Source is similar to the predicate high dose rate brachytherapy source, the Source Production and Equipment Company Model M-19 (K052947) that utilizes photons from ^{192}Iridium. See Sections 12.1 Comparison Table with Predicate Device (Similarities and Differences) and section 12.2 Product Information for Predicate Device.

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

Ms. Jennifer Williams
Official Regulatory Correspondent
Oncology Systems, Inc.
206 N. Randolph Street, Suite 301
CHAMPAIGN IL 61820

NOV 20 2009

Re: K092522
Trade/Device Name: Oncology Systems, Inc. Model ACU-007S
^{192}Iridium Brachytherapy Source
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: August 13, 2009
Received: August 31, 2009

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 (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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ONCOLOGY SYSTEMS

206 N. Randolph Street, Suite 301
Champaign, IL 61820

510(k) Number (if known): K092522

Device Name: Oncology Systems, Inc. Model ACU-007S ^{192}Iridium Brachytherapy Source

Indications for Use:

Oncology Systems Model ACU-007S Source Assembly, with an individual activity up to 12Ci, is indicated for temporary interstitial, intracavitary, intraluminal or intraoperative or surface application to treat selected localized tumors. This source can be used as primary treatment for a variety of anatomical sites commonly treated with high dose rate brachytherapy, including the cervix, vagina, endometrium, rectum, esophagus, bronchus, head and neck, bile duct brain, skin, prostate, lung, pancreas, and breast and for treatment of sarcomas and for intraoperative radiation therapy.

This source may be used concurrently with or following treatment with other interventions, 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 ___X___ (Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092522