APR

Section 5
510(k) Summary

Section 807.92(a)

K052947

(1) Submitter

Source Production & Equipment Co., Inc.
113 Teal Street
St. Rose, LA 70087

Tel: 504.464.9471
Fax: 504.467.7685

Establishment Registration No.: to be Applied For

Contact Person: John J. Munro III
Vice President
e-mail: johnm@spec150.com

(2) Device Name:

Classification Name: Radionuclide Brachytherapy Source (892.5730) (90 KXK)

Common or Usual Name: Brachytherapy Source Assembly

Proprietary Name: SPEC Model M-19

(3) Legally Marketed Predicate Devices:

Varian Medical Systems GammaMed 232, cleared under 510(k) number K030745 dated 12 March 2003, and

Nucletron Corp. Model 105.002, cleared under 510(k) number K953946 dated 13 August 1996, and

Alpha-Omega Services, Inc. Model CSN0010-192, cleared under 510(k) number K991571 dated 22 February 2000

(4) Description of SPEC Model M-19 ^{192}Iridium Brachytherapy Source:

SPEC Model M-19 is a singly-encapsulated ^{192}Iridium Brachytherapy Source. It consists of a stainless steel capsule containing a solid radioactive ^{192}Iridium pellet. The pellet is sealed in a stainless steel capsule that is attached to a cable to permit manipulation by the remote afterloading system.

(5) Intended Use

The intended use of SPEC Model M-19 Brachytherapy Source is for the treatment of cancer by temporary interstitial, intracavitary, intraluminal, intraoperative or surface irradiation.

(6) Technological Characteristics:

SPEC Model M-19 ^{192}Iridium Brachytherapy Source is similar to the predicate high dose rate brachytherapy sources that utilize photons from ^{192}Iridium.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

Mr. John J. Munro III
Vice President
Source Production & Equipment Co., Inc.
113 Teal Street
ST. ROSE LA 70087

Re: K052947
Trade/Device Name: Model M-19 ^{192}Iridium Brachytherapy Source
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: JAQ and KXK
Dated: March 10, 2006
Received: March 13, 2006

Dear Mr. Munro:

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: K052947

Device Name: Source Production & Equipment Co., Inc. Model M-19 ^{192}Iridium Brachytherapy Source

Indications for Use:

Source Production & Equipment Co., Inc. (SPEC) Model M-19 Source Assembly, with individual activity up to 12 Ci, 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 external beam radiation therapy.

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052947

(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 CFR 801.109)

(Optional Format 1-2-96)