DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 17, 2016

Source Production and Equipment Co., Inc.
% Ms. Kelley Richardt
Regulatory and Quality Manager
113 Teal Street
SAINT ROSE LA 70087

Re: K161396
Trade/Device Name: Source Production & Equipment Co., Inc. Model M23 169Ytterbium Brachytherapy Source
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: May 16, 2016
Received: May 19, 2016

Dear Ms. Richardt:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161396

Device Name
Source Production & Equipment Co., Inc. Model M23 169Ytterbium Brachytherapy Source

Indications for Use *(Describe)*

Source Production & Equipment Co., Inc. (SPEC) Model M23 Source Assembly, with individual activity up to 27 Ci, is indicated for temporary interstitial, intracavitary, intraluminal, 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5
510(k) Summary

Section 807.92(a)

(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.: 1000437833

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 M23

(3) Legally Marketed Predicate Device:

Implant Sciences Corp. Model HDR-4140, cleared under 510(k) number K042864 dated 06 Jan 2005 as described in Section 12

(4) Description of SPEC Model M23 ^{169}Ytterbium Brachytherapy Source:

SPEC Model M23 is a singly-encapsulated ^{169}Ytterbium Brachytherapy Source. It consists of a stainless steel capsule containing solid radioactive ^{169}Ytterbium Oxide pellets. The pellets are 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 M23 Brachytherapy Source is for the treatment of cancer by temporary interstitial, intracavitary, intraluminal, intraoperative or surface irradiation.

(6) Technological Characteristics:

SPEC Model M23 ^{169}Ytterbium Brachytherapy Source is similar to the predicate high dose rate brachytherapy source that utilizes photons from ^{169}Ytterbium.

Technological Characteristic	Source Production & Equipment Co., Inc. (SPEC) M23 ^{169}Ytterbium High Dose Rate Brachytherapy Source	Implant Sciences Corp. HDR-4140 ^{169}Ytterbium High Dose Rate Brachytherapy Source
Design	The source consists of solid ^{169}Ytterbium Oxide pellets (Configuration H: 0.6 mm dia x 3.5 mm long; Configuration P: 0.6 mm dia x 2.0 mm long)) singly encapsulated in stainless steel (Configuration H: 0.9 mm dia x 4.8 mm long; Configuration P: 0.9 mm dia x 3.3 mm long) and welded to a 7x7+4 stranded stainless steel cable (0.9 mm dia x 2100 mm long).	The source consists of solid ^{169}Ytterbium pellets (0.65 mm dia x 4.0 mm overall length) doubly encapsulated. The inner capsule (0.8 mm dia x 4.5 mm lg) is titanium and the outer capsule (0.98 mm dia x 5.9 mm long) is stainless steel. The outer capsule is welded to a 7x7 stranded stainless steel cable (0.9 mm dia x 2100 mm long).
Materials Radionuclide Encapsulation Cable	 ^{169}Ytterbium Stainless Steel Stainless Steel	 ^{169}Ytterbium Titanium & Stainless Steel Stainless Steel
Performance Dosimetry (TG43) Dose Rate Const (λ) Anisotropy (ϕ_{av}):	 Configuration H Configuration P 1.17 cGy h^{-1} U^{-1} 1.18 cGy h^{-1} U^{-1} 0.94 0.94	 1.18 cGy h^{-1} U^{-1} 0.94
Sterility	This source assembly never directly contacts the patient; sterility is not required.	This source assembly never directly contacts the patient; sterility is not required.
Biocompatibility	This source assembly never directly contacts the patient; biocompatibility assessment is not applicable. The outside of the entire assembly is fabricated from stainless steel, which is a biocompatible material.	This source assembly never directly contacts the patient; biocompatibility assessment is not applicable. The outside of the entire assembly is fabricated from stainless steel, which is a biocompatible material.
Mechanical Safety	ANSI N43.6 Class C64212 Applied for Louisiana Registration	ANSI N43.6 Class C64212
Chemical Safety	This source assembly never directly contacts the patient; chemical safety assessment is not applicable. The outside of the entire assembly is fabricated from stainless steel, which is will not chemically react with body tissue.	This source assembly never directly contacts the patient; chemical safety assessment is not applicable. The outside of the entire assembly is fabricated from stainless steel, which is will not chemically react with body tissue.
Energy Delivered	^{169}Ytterbium (half-life: 32.02 days) which decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium and stainless steel walls of the source encapsulation. The principal photon emissions are 50 and 58 keV x-rays and a 63, 94, 111, 131, 177, 198, 260 and 308 keV gammas.	^{169}Ytterbium (half-life: 32.02 days) which decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium and stainless steel walls of the source encapsulation. The principal photon emissions are 50 and 58 keV x-rays and a 63, 94, 111, 131, 177, 198, 260 and 308 keV gammas.
Compatibility with Environment and	^{169}Ytterbium is a radioactive material and should be strictly controlled.	^{169}Ytterbium is a radioactive material and should be strictly controlled.

Other Devices	The source should only be used following the conditions and limitations specified by the licensing authority (NRC or Agreement State). The source should be stored in a shielded container, either the remote afterloader with which it is used or the transport container in which it is delivered. If any source cannot be accounted for, the loss should be reported to the federal or state licensing agency. Store at normal room temperature. When disposal is indicated, radioactive material should be transferred to an authorized recipient, typically the source supplier. Radioactive material should never be disposed of in normal waste.	The source should only be used following the conditions and limitations specified by the licensing authority (NRC or Agreement State). The source should be stored in a shielded container, either the remote afterloader with which it is used or the transport container in which it is delivered. If any source cannot be accounted for, the loss should be reported to the federal or state licensing agency. Store at normal room temperature. When disposal is indicated, radioactive material should be transferred to an authorized recipient, typically the source supplier. Radioactive material should never be disposed of in normal waste.
Where Used	This source should only be used within a properly shielded enclosure designed to maintain radiation dose rates outside the enclosure within regulatory limits.	This source should only be used within a properly shielded enclosure designed to maintain radiation dose rates outside the enclosure within regulatory limits.
Standards Met Mechanical Dosimetry	 ANSI N43.6 AAPM TG-43	 ANSI N43.6 AAPM TG-43
Electrical Safety	Not Applicable	Not Applicable
Thermal Safety	Not Applicable	Not Applicable
Radiation Safety	This ^{169}Ytterbium source is radioactive, and appropriate precautions must be taken during handling to minimize radiation exposure to personnel. Personnel monitoring is required. This source should only be used within a properly shielded enclosure designed to maintain radiation dose rates outside the enclosure within regulatory limits. In circumstances where emergency operations must be performed within protective barriers, the operator should use proper applicators, maintain safe working distances and work as rapidly as safely possible to minimize radiation exposure.	This ^{169}Ytterbium source is radioactive, and appropriate precautions must be taken during handling to minimize radiation exposure to personnel. Personnel monitoring is required. This source should only be used within a properly shielded enclosure designed to maintain radiation dose rates outside the enclosure within regulatory limits. In circumstances where emergency operations must be performed within protective barriers, the operator should use proper applicators, maintain safe working distances and work as rapidly as safely possible to minimize radiation exposure.

Section 807.92(b)

(1) Nonclinical Tests

Physical Testing

The Model M23 source has been subjected to the tests specified in American National Standard (ANSI) N43.6 and International Organization for Standardization (ISO) Standard 2919, as referenced in the FDA "Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources" dated 2 August 2000.

Prototype sources were subjected to the tests specified in ANSI N43.6-2007 and ISO 2919-2012 and have equaled or exceeded the requirements corresponding to a classification of C53211, which is the requirement for brachytherapy sources. Th3 testing performed is equivalent to the physical testing of the predicate device.

Tensile Testing

Prototype sources were subjected to a tensile load to failure with the minimum failure load of 85 N (19 lb). The maximum force that can be applied by the Varian GammaMed Plus Afterloader is 16 N (3.6 lb). Therefore, this test load was more than 5 times the maximum force that can be applied by the Varian GammaMed Plus Afterloader.

In addition, prototypes were subjected to a series of tensile fatigue tests consisting of:

- a tensile load in excess of 40 N (9 lb), which is more than 2.5 times the maximum force than can be applied to the cable by the Varian GammaMed Plus Afterloader
- ten sequential applications of a tensile load of in excess of 16 N (3.6 lbs) which is more than the maximum load that can be applied by the Varian GammaMed Plus Afterloader, and then
- a tensile load in excess of 40 N (9 lb), which is more than 2.5 times the maximum force than can be applied to the cable by the Varian GammaMed Plus Afterloader
- and finally a tensile load to failure of each of the welds of the source assembly, where the the minimum failure load was 84 N (19 lb) which is more than 5 times the maximum force that can be applied by the Varian GammaMed Plus Afterloader.

It is concluded that that the tensile strength of this source assemble is sufficient for its intended application. This is equivalent to or better than the tensile testing of the predicate device.

Operational Testing

A prototype source assembly was subjected to a curved pathway performance test consisting of driving the source cable through a series of "S" and "U" curves with a variety of radii which simulate the various pathways of applicators used with the GammaMed Plus Afterloader. The source capsule and cable successfully negotiated all of these pathways. There was no damage to the M13 source assembly.