



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

July 6, 2016

Re: K161395
Trade/Device Name: Source Production and Equipment Co., Inc. Model M13 ¹⁹²Iridium
Brachytherapy Source
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXX
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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, light gray watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)
K161395

Device Name
Source Production & Equipment Co., Inc. Model M13 192Iridium Brachytherapy Source

Indications for Use (Describe)

Source Production & Equipment Co., Inc. Model M13 192Iridium Brachytherapy Source, with individual activity up to 12 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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Section 5 510(k) Summary

Section 807.92(a)

(1) Submitter Source Production & Equipment Co., Inc. Tel: 504.464.9471
113 Teal Street Fax: 504.467.7685
St. Rose, LA 70087

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: Source Production & Equipment Co., Inc. Model M13
¹⁹²Iridium Brachytherapy Source

(3) Legally Marketed Predicate Device:

Source Production & Equipment Co., Inc. Model M15,
cleared under 510(k) number K132969 dated 02 January
2014

(4) Description of Source Production & Equipment Co., Inc. Model M13 ¹⁹²Iridium
Brachytherapy Source:

Source Production & Equipment Co., Inc. Model M13 ¹⁹²Iridium Brachytherapy Source is a singly-encapsulated ¹⁹²Iridium Brachytherapy Source. It consists of a stainless steel capsule containing a solid radioactive ¹⁹²Iridium 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 Source Production & Equipment Co., Inc. Model M13 ¹⁹²Iridium Brachytherapy Source is for the treatment of cancer by temporary interstitial, intracavitary, intraluminal, intraoperative or surface irradiation.

(6) Technological Characteristics:

Source Production & Equipment Co., Inc. Model M13 ¹⁹²Iridium Brachytherapy Source is similar to the predicate high dose rate brachytherapy source that utilizes photons from ¹⁹²Iridium.

Technological Characteristic	Source Production & Equipment Co., Inc. (SPEC) M13 ¹⁹² Iridium High Dose Rate Brachytherapy Source	Source Production & Equipment Co., Inc. (SPEC) M15 ¹⁹² Iridium High Dose Rate Brachytherapy Source
Design	The source consists of a solid ¹⁹² Iridium pellet (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 a solid ¹⁹² Iridium pellet (0.6 mm dia x 3.5 mm long) singly encapsulated in stainless steel (1.1 mm dia x 4.8 mm long) and welded to a 7x7 stranded stainless steel cable (1.1 mm dia x 2000 mm long).
Materials Radionuclide Encapsulation Cable	¹⁹² Iridium Stainless Steel Stainless Steel	¹⁹² Iridium Stainless Steel Stainless Steel
Performance Dosimetry (TG43) Dose Rate Const (λ) Anisotropy (ϕ_{av}):	Configuration H Configuration P 1.11 cGy h ⁻¹ U ⁻¹ 1.12 cGy h ⁻¹ U ⁻¹ 0.97 0.97	1.11 cGy h ⁻¹ U ⁻¹ 0.97
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 C53211 Applied for Louisiana Registration	ANSI N43.6 Class C53211 Louisiana Sealed Source Registration LA-0612-S-117-S
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	¹⁹² Iridium (half-life: 73.81 days) which decays by beta emission and electron capture with the emission of characteristic photons and electrons. The betas and electrons are absorbed by the stainless steel wall of the source capsule. The	¹⁹² Iridium (half-life: 73.81 days) which decays by beta emission and electron capture with the emission of characteristic photons and electrons. The betas and electrons are absorbed by the stainless steel wall of the source capsule. The

	principal photon emissions are 67 keV x-rays and 201, 311, 467, and 603 keV gammas.	principal photon emissions are 67 keV x-rays and 201, 311, 467, and 603 keV gammas.
Compatibility with Environment and Other Devices	<p>¹⁹²Iridium is a radioactive material and should be strictly controlled.</p> <p>The source should only be used following the conditions and limitations specified by the licensing authority (NRC or Agreement State).</p> <p>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.</p> <p>If any source cannot be accounted for, the loss should be reported to the federal or state licensing agency.</p> <p>Store at normal room temperature.</p> <p>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.</p>	<p>¹⁹²Iridium is a radioactive material and should be strictly controlled.</p> <p>The source should only be used following the conditions and limitations specified by the licensing authority (NRC or Agreement State).</p> <p>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.</p> <p>If any source cannot be accounted for, the loss should be reported to the federal or state licensing agency.</p> <p>Store at normal room temperature.</p> <p>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.</p>
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	<p>This ¹⁹²Iridium source is radioactive, and appropriate precautions must be taken during handling to minimize radiation exposure to personnel. Personnel monitoring is required.</p> <p>This source should only be used within a properly shielded enclosure designed to maintain radiation dose rates outside the enclosure within regulatory limits.</p> <p>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.</p>	<p>This ¹⁹²Iridium source is radioactive, and appropriate precautions must be taken during handling to minimize radiation exposure to personnel. Personnel monitoring is required.</p> <p>This source should only be used within a properly shielded enclosure designed to maintain radiation dose rates outside the enclosure within regulatory limits.</p> <p>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.</p>

Section 807.92(b)

(1) Nonclinical Tests

Physical Testing

The Model M13 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. This 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.

Subsequently, the same source assembly was subjected to an endurance performance test in a simulated GammaMed Plus Afterloader, where the source assembly performed more than 35,000 exposure/retract cycles. As a result of these tests, there was no failure of the source cable, the source capsule or the connection of the source capsule to the source cable.

This is equivalent to the physical testing of the predicate device.

Dosimetry

The dose distribution around the Model M13 source was calculated by Monte Carlo simulation in accordance with the recommendations of the American Association of Physicists in Medicine and the European Society for Therapeutic Radiation Oncology.¹ This is equivalent to the dosimetry of the predicate device.

(2) Clinical Tests

Not Applicable

(3) Conclusions

The results of the nonclinical physical, tensile, operational tests and the dosimetric analysis, demonstrate that the SPEC Model M13 High Dose Rate Brachytherapy Source is as safe, as effective, and performs as well or better than the legally marketed predicate device, SPEC Model M15 High Dose Rate Brachytherapy Source.

¹ Perez-Calatayud J, Ballester F, Das RK, Dewerd LA, Ibbott GS, Meigooni AS, Ouhib Z, Rivard MJ, Sloboda RS, Williamson JF, Dose calculation for photon-emitting brachytherapy sources with average energy higher than 50 keV: report of the AAPM and ESTRO, Med Phys. 2012 May;39(5):2904-29