K102811

JUN - 2 2011

510(k) Summary

1. General Information

510(k) Owner:	Alpha-Omega Services, Inc. 9156 Rose Street Bellflower, California 90706 Tel: (562) 804-0604 Fax: (562) 804-0610
Contact Person:	Bob A. Robnett Director Regulatory Affairs & Quality
Date:	September 20, 2010
Trade Name:	AOS Orion Ir-192 Source Cable
Common/Usual Name:	Radionuclide Brachytherapy Source
Classification Name:	Radionuclide Brachytherapy Source 21 CFR 892.5730, Class II, Product Code: KXK
Establishment Registration Numbers:	2022694, 3003660614
Special Controls	None
Substantial Equivalence:	K092804 MicroSelectron HDR Version 2 K061354 MicroSelectron V3

2. Device Description

The AOS Orion Ir-192 Source Cable (Model No. CSO0012-192) is a nominal 12 Curie Iridium-192 source cable for use in the Nucletron microSelectron HDR Version 2 (Model No. 105.99) and the Nucletron microSelectron V3 (Model No. 106.990) Remote Afterloaders.

3. Intended Use

The AOS Orion Ir-192 Source Cable is a sealed radionuclide brachytherapy source to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy. This device is the replaceable Ir-192 source for the Nucletron Corp. MicroSelectron HDR V2 and V3 Afterloaders.

4. Performance Test

4.1. Compatibility and Mechanical

The mechanical strength and compatibility of the AOS Orion Ir-192 Source Cable has been verified through a series of tests demonstrating worst case scenarios. Testing was successfully completed as prescribed and all the acceptance criteria have been met. The Orion Cable has been demonstrated to be compatible for use with the Nucletron microSelectron V2 and Nucletron microSelectron V3 HDR Remote Afterloaders.

4.2. ISO 2919 and Cable/Weld Strength Testing

The AOS Orion Ir-192 Source Cable has been tested and acceptance criteria outlined in the ISO 2919 and ISO 9978 standards. In addition, the Orion Cable's weld and cable strength have been

tested and are equivalent to the predicate's performance.

5. Substantial Equivalence

Predicate Information	New Device	Predicate 1	Predicate 2
Device Name Model Number 510(k)	AOS Orion Ir-192 Source Cable Patent Pending CSO0012-192	MicroSelectron HDR Version 2 105.999 K092804	MicroSelectron V3 106.990 K061354
Registry of Sealed Source & Device	Not yet submitted. Awaiting 510(k) approval.	MD-0497-S-107-S	MD-0497-S-107-S
Diameter	0.9mm	0.9mm	0.9mm
Length	2022mm	2022mm	2022mm
Cable Type[1]	1x7 Nitinol Inner Core with a 6 Wire Crosslaid Stainless Steel Outer Wrap	Section 1: 19 Stands Crosslaid Section 2: 7x7 Stranded	Section 1: 19 Stands Crosslaid Section 2: 7x7 Stranded
Materials[2]	Stainless Steel/Nitinol	Stainless Steel	Stainless Steel
Predicate Information	New Device	Predicate 1	Predicate 2
Seal Method	Laser Weld	Laser Weld	Laser Weld
Cable Strength	≥ 200 Newtons	≥ 200 Newtons	≥ 200 Newtons
Welds Strength	Able to withstand 15 Newtons for 3 minutes	Able to withstand 15 Newtons for 3 minutes	Able to withstand 15 Newtons for 3 minutes
Range of Motion	Radius of ≥ 12mm	Radius of ≥ 15mm	Radius of ≥ 15mm
Isotope	Iridium-192	Iridium-192	Iridium-192
Nominal Activity	12 Curies	12 Curies	12 Curies
Tested Transfer Cycles	100,000	100,000	100,000
Certified Cycles	25,000	25,000	25,000
Recommended Cycles	5000	5000	5000

[1] The AOS Orion Ir-192 Source Cable is a one piece cable constructed of a 1x7 nitinol inner core with a 6 Wire Crosslaid Stainless Steel Outer Wrap. Performance testing has demonstrated that this design provides the same strength and flexibility as the 2 piece predicate cable.

[2] The addition of nitinol strands provides the required flexibility without the need for a smaller diameter cable attachment as found on the predicate cable.

6. Conclusion

Based on the above information, the AOS Orion Ir-192 Source Cable has been demonstrated to be equivalent to the source cable used in both predicate devices.

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

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Mr. Bob A. Robnett
Director Regulatory Affairs & Quality
Alpha-Omega Services, Inc.
9156 Rose Street, P.O. Box 789
BELLFLOWER CA 90706

Re: K102811
Trade/Device Name: AOS Orion Ir-192 Source Cable
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: May 2, 2011
Received: May 3, 2011

Dear Mr. Robnett:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: AOS Orion Ir-192 Source Cable

Indications for Use: The AOS Orion Ir-192 Source Cable is a sealed radionuclide brachytherapy source to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy. This device is the replaceable Ir-192 source for the Nucletron Corp. MicroSelectron HDR V2 and V3 Afterloaders.

Prescription Use __Yes__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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