

K062824

**510(k) Summary  
AOS Universal Connecting Guide Tube**

JUL - 3 2007

Alpha-Omega Services, Inc.  
9156 Rose Street  
Bellflower, CA 90706  
Tel: (800) 346-7894  
Fax: (562) 804-0604  
Bob A. Robnett  
July 2006

**DEVICE NAME**

AOS Universal Connecting Guide Tube

**PROPRIETARY NAME**

AOS Universal Connecting Guide Tube

**COMMON/USUAL NAME**

Afterloader Coupling Catheter

**CLASSIFICATION NAME**

21 CFR 892.5700, Product Code: JAQ, Class II

**PREDICATED DEVICES**

AOS Universal Connecting Guide Tube, K964910

**DESCRIPTION**

Alpha-Omega Services (AOS) Universal Connecting Guide Tube is used to connect any Alpha-Omega applicator accessory with Luer Lock fittings to a High Dose Rate (HDR) Afterloader.

The Alpha-Omega universal Connecting Guide Tube is supplied in the nominal length of 100cm. The distal end is a female luer lock, which is used to connect to the male end of the Luer Lock applicator/accessory or to the Extension Adaptor and Needle combination, providing an unobstructed pathway for the source wire or cable from the Afterloader to the tip of the applicator/accessory.

**INTENDED USE**

The purpose of the AOS Universal Connecting Guide Tube is to provide an enclosed coupling between a Remote High Dose Rate Afterloader and patient needles and/or other devices to apply radionuclide source into the body or to the surface of the body for radiation therapy.

**CONTRAINDICATIONS**

Single Use Device

**PERFORMANCE STANDARDS**

No performance Standards for Brachytherapy Applicators are in effect at this date.

**SUBSTANTIAL EQUIVALENCE**

The AOS Universal Connecting Guide Tube are substantial equivalence to the AOS Universal Connecting Guide Tube, K964910. A comparison summary of technological characteristics is Connecting Guide Tube, K964910. A comparison summary of technological characteristics is listed below. See Section 7 Device Description for detailed information.

<b>NEW DEVICE:</b>	AOS Universal Connecting Guide Tube
<b>PREDICATE:</b>	AOS Universal Connecting Guide Tube, K964910
<b>DESIGN:</b>	Both the new and predicate device share the same design
<b>MATERIAL:</b>	Both the new and predicate device are constructed of the same materials
<b>SINGLE USE:</b>	Both the new and predicate device are Single Use Only.
<b>STERILE:</b>	New device is sterile. Predicate is non-sterile

**Conclusions**

The Conclusion drawn from the above is that the AOS Universal Connecting Guide Tube are equivalent in safety and efficacy to their predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

JUL - 3 2007

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

Re: K062824  
Trade/Device Name: AOS Universal Connecting Guide Tube  
Regulation Number: 21 CFR 892.5700  
Regulation Name: Remote controlled radio-nuclide applicator system  
Regulatory Class: II  
Product Code: JAQ  
Dated: June 19, 2007  
Received: June 20, 2007

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 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.



*Protecting and Promoting Public Health*

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.

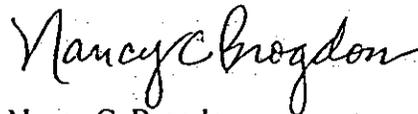
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications For Use

510(k) Number (if known): K062824

Device Name: AOS Universal Connecting Guide Tube

**Indications For Use:** The purpose of the AOS Universal Connecting Guide Tube is to provide an enclosed coupling between a Remote High Dose Rate Afterloader and patient needles and/or other devices to apply radionuclide source into the body or to the surface of the body for radiation therapy.

**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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation

Nancy Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K062824