

K002823

**510(k) Summary**  
**AOS Interstitial Templates, Needles & Accessories**

Alpha-Omega Services, Inc.  
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Fax: (562) 804-0604  
Bob A. Robnett  
July 2006

MAY 29 2007

**DEVICE NAME**

AOS Interstitial Templates, Needles & Accessories

**PROPRIETARY NAME**

AOS Interstitial Templates, Needles & Accessories

**COMMON/USUAL NAME**

Interstitial Template

**CLASSIFICATION**

System, Applicator, Radionuclide, Remote-Controlled  
21 CFR 892.5700, Product Code: JAQ, Class II

**PREDICATED DEVICES**

AOS Prostate Template, Rectal Template, GYN Template (Preamendment, See Appendix A)

AOS Template Needle (Preamendment, See Appendix A)

AOS Template Tip (Preamendment, See Appendix A)

**DESCRIPTION**

Alpha-Omega Services (AOS) Templates, Template Needles and Accessories provide a fixed array of needles, via the template. AOS Templates are made of silicone, with holes in a circular pattern, typically spaced 1 cm (center-to-center). AOS templates are supplies in various sizes to accommodate treatment sites as prostate, rectum, or vagina.

The Template is sutured in place and Template Needles are inserted into the holes of the Template. The number and type of Template needles is dependant on the model of Afterloader or if the manual LDR method is used, which consists of strands or ribbons of discrete sources.

Additional accessories are required in vaginal cases. The AOS GYN Templates have a large hole, with a guide strip. The matching AOS Vaginal Guide Tube is inserted in this hole, lining up the guide strip with the guide groove. The Vaginal

Guide is pushed to the desired depth and the large O-Ring is slipped over the Vaginal Guide. The AOS collar is then used to push the O-Ring along the Vaginal Guide until it can be slipped over and on to the grooved ring on the Template. The O-Ring's elasticity tightens down and provides sufficient tension to hold the Vaginal Guide in place. Each Vaginal Guide has six (6) Needle grooves for the insertion of additional Template Needles as required.

Template Needles may have a plain end or some sort of attachment device, such as a female luer adaptor if an Afterloader is to be used. If the Manual LDR method is used, typically a Template Needles with or without a collar is chosen. Where an Afterloader is used, the Template Needles are connected to the HDR Afterloader via an appropriate connector. If the Template Needle has a female Luer Adaptor on the proximal end, connection to the AOS Universal Connecting Guide Tube (K964910) provides an unobstructed pathway for the source wire or cable from the Afterloader to the appropriate distance as determined by the Afterloader. Some Afterloaders provide a transfer tube, which is connected, to the Afterloader while the other end slips over the plain end of the Template Needles and is tightened down to hold and connect the Template Needle.

#### ***INTENDED USE***

The purpose of AOS Interstitial Templates, Needles, and Accessories is to provide an enclosed pathway for application of radioactive source(s) into the body or surface of the body for radiation therapy (brachtherapy).

#### ***CONTRAINDICATIONS***

Single Use Device

#### ***PERFORMANCE STANDARDS***

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

#### ***SUBSTANTIAL EQUIVALENCE***

AOS Interstitial Templates, Needles & Accessories are substantial equivalence to the AOS Implant Tube (Preamendment), AOS Implant Needle (Preamendment), and AOS Retaining Button (Preamendment). A comparison summary of technological characteristics is listed below. See Sections 7 Device Description for detailed information.

<b><i>NEW DEVICE:</i></b>	AOS Interstitial Templates
<b><i>PREDICATE:</i></b>	AOS Prostate Template, Rectal Template, GYN Template
<b><i>DESIGN:</i></b>	Both the new and predicate device share the same design
<b><i>MATERIAL:</i></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
<b>NEW DEVICE:</b>	AOS Interstitial Needles
<b>PREDICATE:</b>	AOS Template Needles
<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
<b>NEW DEVICE:</b>	AOS Interstitial Accessories
<b>PREDICATE:</b>	AOS Needle Tips
<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 Interstitial Templates, Needles & Accessories 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

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

MAY 29 2007

Re: K062823

Trade/Device Name: AOS Interstitial Templates, Needles & Accessories  
Regulation Number: 21 CFR 892.5700  
Regulation Name: Remote controlled radio-nuclide applicator system  
Regulation Number: 21 CFR 892.5710  
Regulation Name: Radiation therapy beam-shaping block  
Regulatory Class: II  
Product Code: JAQ and KXK  
Dated: May 1, 2007  
Received: May 3, 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.

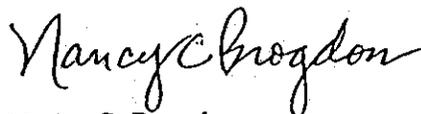
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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): K062823

Device Name: AOS Interstitial Templates, Needles & Accessories

**Indications For Use:** The purpose of AOS Interstitial Templates, Needles and Accessories is to provide an enclosed pathway for application of radioactive source(s) into the body or surface of the body for radiation therapy (brachytherapy).

**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

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K062823