Alpha-Omega Services, Inc.
% Bob Robnett
Director Regulatory Affairs & Quality Assurance
9156 Rose Street
BELLFLOWER, CA 90706

July 10, 2024

Re: K233628
Trade/Device Name: AOS Interstitial Templates, Needles, and Accessories
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: November 10, 2023
Received: November 13, 2023

Dear Bob 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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming

product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233628

Device Name

AOS Interstitial Templates, Needles, and Accessories (Various)

Indications for Use *(Describe)*

AOS Interstitial Templates, Needles, and Accessories are indicated for use in adults where Brachytherapy of the cervix or prostate is an accepted clinical practice.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K233628

510(k) Summary

Prepared on: 2024-06-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Alpha-Omega Services, Inc.
Applicant Address	9156 Rose Street Bellflower CA 90706 United States
Applicant Contact Telephone	562-804-0604
Applicant Contact	Mr. Bob Robnett
Applicant Contact Email	brobnett@alphaomegaserv.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	AOS Interstitial Templates, Needles, and Accessories
Common Name	Remote controlled radionuclide applicator system
Classification Name	System, Applicator, Radionuclide, Remote-Controlled
Regulation Number	892.5700
Product Code	JAQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K062823	AOS Interstitial Templates, Needles & Accessories	JAQ

Device Description Summary

21 CFR 807.92(a)(4)

AOS Interstitial Templates, Needles, and Accessories are designed for interstitial Brachytherapy treatments of the cervix and prostate. The Templates are designed to be sutured to the perineal area in order to fix the geometry of the Template Needles placed into the cervix or prostate.

AOS Templates are made of silicone, with holes in a circular pattern, typically spaced 1 cm (Center-to center). AOS Templates are supplied in two configurations to accommodate a prostate or GYN treatment.

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 dependent on the model of Afterloader.

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.

Where an Afterloader is used, the Template Needles are connected to the 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, P/N SGU0007, 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 Needle and is tightened down to hold and connect the Template Needle.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

AOS Interstitial Templates, Needles, and Accessories are indicated for use in adults where Brachytherapy of the cervix or prostate is an accepted clinical practice.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Wording of the Indications for Use was reworded for clarification, but the Indications for Use have not changed.

Technological Comparison 21 CFR 807.92(a)(6)

The predicate device was marketed as sterile. Sterilization is now completed by the end user. All other technological characteristics are the same as the predicate device.

NOTE: The following devices originally included in the predicate 510(k) K062823 have been discontinued due to market demands:
CNT0003-001, Needle Cap
CNT0004-001, Needle Cap
NFD0001-000, FlexiGuide Needle
NFV0001-000, FlexiGuide Needle
NFV0002-000, FlexiGuide Needle
NFV0003-000, FlexiGuide Needle
NFW0001-000, FlexiGuide Needle
NTD0001-000, Template Needle
NTD0002-000, Template Needle
NTD0003-000, Template Needle
NTD0004-000, Template Needle
NTD0005-000, Template Needle
NTD0006-000, Template Needle
OTD0001-000, O-Ring (Was previously sold separately)
SNF0001-000, Stylet
SNF0002-000, Stylet
SNF0003-000, Stylet
SNT0001-000, Stylet
SNT0002-000, Stylet
SNT0003-000, Stylet
TGD0002-000, GYN-2 Template
TNS0001-000, Needle Tip
TRD0001-000, Rectal Template
TRD0002-000, Rectal Template

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical testing were not performed as device is identical to the predicate device.

Nonclinical testing were not performed as device is identical to the predicate device.

Nonclinical testing were not performed as device is identical to the predicate device.