



ORIGINAL

Mr. John Jankovich
U.S. Nuclear Regulatory Commission
Source Safety and Security Branch
Office of Federal and State Materials & Environmental Management Programs
Mail Stop T:8F3
Washington, DC 20555

Our reference:

GA-0497-S-107-S
GA-0497-D-108-S
GA-0497-D-114-S

Your reference:

GA-0497-S-107-S
GA-0497-D-108-S
GA-0497-D-114-S

Date:

August 29, 2013

Dear Mr. Jankovich:

Please be informed that Nucletron, an Elekta Company of The Netherlands has established a manufacturing agreement with Alpha-Omega Services, Inc (AOS) of Bellflower CA. Nucletron, an Elekta Company, has contracted AOS to manufacture Nucletron's Iridium -192 source used in the Nucletron mHDR Model 105.999 (V2) and 106.990 (V3) afterloaders.

As per NUREG-1556 Vol. 3 Revision 1 "*Applications for Sealed Source and Device Evaluation and Registration*," please find enclosed the ISO 13485 certification and FDA Facility Registration for AOS, Inc. in lieu of a full set of QA/QC plans.

- There has been no change in the source design. The same design and manufacturing processes including materials, dimensions within stated tolerances, manufacturing methods, assembly methods and labeling used by Mallinckrodt and QSA Global will be used by AOS Inc.
- There is no change in the maximum source activity.
- All units are leak tested to 185 Bq (0.005 μ Ci).
- Final inspection is performed in accordance with approved written instructions. Such inspection and testing has been designed to ensure that each device meets specifications for safety, and effectiveness.

Elekta respectfully requests an amendment to the above Sealed Source and Device Registries to reflect this change. For the amended SS&D sheets (source and device), please designate the source model as Model 105.002 manufactured by Mallinckrodt Medical BV, Petten, Holland or QSA Global, Burlington, MA or Alpha-Omega Services, Edgerly, LA.

AOS, Inc. intends to be operational and ready for distribution by October 1, 2013. Elekta Inc. and Nucletron, an Elekta Company, appreciate the NRC's efforts to help achieve this goal.

Any questions regarding the above matter should be directed to the undersigned at 770-670-2518 or via email at debbie.bensen@elekta.com.

Sincerely,

A handwritten signature in blue ink that reads "Debra L. Bensen". The signature is written in a cursive, flowing style.

Debra L. Bensen
RSO

Enclosures: AOS, Inc. ISO 13485 Certificate
AOS, Inc. FDA Establishment Registration & Device Listings for Bellflower, CA and Edgerly, LA locations



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

**Alpha-Omega Services, Inc.
9156 Rose Street
Bellflower
California
90706
USA**

Holds Certificate No: **FM 574387**

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

Design, manufacture and distribution of brachytherapy medical devices and associated accessories.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally Registered: **11/02/2011**

Latest Issue: **08/13/2012**

Expiry Date: **11/01/2014**



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.
Americas Headquarters: BSI Group America Inc., 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.
A Member of the BSI Group of Companies.

Certificate No: **FM 574387**

Location

Registered Activities

Alpha-Omega Services, Inc.
9156 Rose Street
Bellflower
California
90706
USA

Design, manufacture and distribution of brachytherapy medical devices and associated accessories.

Alpha-Omega Services, Inc.
1282 Bigwoods-Starks Road
Edgerly
Louisiana
70668
USA

Manufacture and distribution of brachytherapy medical devices and associated accessories.

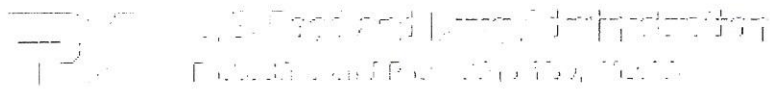
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Establishment Registration & Device Listing

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Establishment:

ALPHA-OMEGA SERVICES, INC.
1282 Big Woods-Stark Rd.
Edgerly (Vinton), LA 70668
Registration Number: 3003660614
Status: Active
Date Of Registration Status: 2013

Owner/Operator:

ALPHA-OMEGA SERVICES
9156 Rose St
Bellflower, CA 90706
Owner/Operator Number: 2022694

Official Correspondent:

Bob A Robnett
ALPHA-OMEGA SERVICES, INC.
9156 Rose St.
Bellflower, CA 90706
Phone: 562-8040604

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Establishment:

ALPHA-OMEGA SERVICES, INC.
9156 Rose St
Bellflower, CA 90706

Registration Number: 2022694

Status: Active

Initial Distributor/Importer: Yes

*Note Firm May Have Additional Establishment Types.

Please Review Listings For Further Information.

Date Of Registration Status: 2013

Owner/Operator:

ALPHA-OMEGA SERVICES
9156 Rose St
Bellflower, CA 90706

Owner/Operator Number: 2022694

Official Correspondent:

Bob A Robnett
9156 Rose St
Bellflower, CA 90706

Phone: 562-8040604

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