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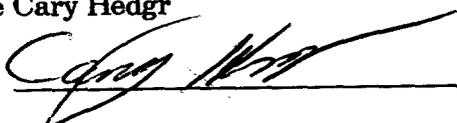
Section 2
Summary & Certification

The following is a Summary & Certification of the AOS Universal Connecting Guide Tube.

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for a Afterloader Coupling Catheter.

Printed Name Cary Hedgr

Signature



Title Operations Manger/Alt. RSO

Date

11-19-96

Alpha-Omega Services, Inc., 9156 Rose St., Bellflower, CA 90706
1-800-346-7894 Fax 310-804-0610

CLASSIFICATION NAME:	Brachytherapy Applicators
COMMON/USUAL NAME:	Afterloader Coupling Catheter
PROPRIETARY NAME:	<i>AOS Universal Connecting Guide Tube</i> for Afterloading Systems.
CLASSIFICATION:	21 CFR Part 892.5700, Product Code: 90-JAQ, Class II
PERFORMANCE STANDARDS:	No Performance Standards for Brachytherapy Applicators are in effect at this date.
PREDICATED DEVICE	Varian Coupling Catheters (K952913) and Omnitron International System (K881665).
INDICATIONS	To provide an enclosed coupling between a Remote High Dose Rate Afterloader and patient needles and/or other devices to apply a radionuclide source into the body or to the surface of the body for radiation therapy.
CONTRAINDICATIONS	Single Use Device. Do not re-clean, re-sterilize device. Any reprocessing may result in changes in the physical characteristics of the device. Do

not counter accepted clinical practice or institution guidelines.

SUBSTANTIAL EQUIVALENCE

The AOS Universal Connecting Guide Tube coupling catheters are substantial equivalence to Varian Coupling catheter (K952913), and Omnitron International Coupling catheter (K881665). Construction and materials are the same for all referenced devices. All devices are listed as single use, provided as non sterile.

CONCLUSIONS

The conclusion drawn from the above is that the AOS Universal Connecting Guide Tube is equivalent in safety and efficacy to its predicate device.