

FEB 22 2000

510(k) Submission, Radionuclide Brachytherapy Source  
Alpha-Omega Services, Inc.

K991571

**Section 2  
Summary 510(k)**

The following is a Summary of the Alpha-Omega Services, Inc., 10 Curie IR-92 Brachytherapy Source for Nucletron Microselection device.

**General Information**

Applicant	Alpha-Omega Services, Inc. 9156 Rose Street Bellflower, California 90706 (800) 346-7894 (562) 804-0610 Fax
Manufacturing Facility	Alpha-Omega Services, Inc. 1282 Big Woods and Starks Rd. Edgerly, LA 70668 (318) 589-5720
Contact Person	Bruce Hedger, President and RSO
Classification Name	Radionuclide Brachytherapy Source.
Common/Usual Name	10 Curie IR-92 Brachytherapy Source for Nucletron Afterloader device.
Proprietary Name	10 Curie Iridium 192 Source, Model CSN0010-192.
Establishment Registration Number	2022694 California, Louisiana registration has been sent in.
Classification	21 CFR 892.5730, Class II, Product Code: JAQ
Special Controls	Product will comply with the nuclear regulatory requirements for the State of Louisiana NRC and US NRC.
Substantial Equivalence	K864210 Nucletron Microselection Source.

The contents of this premarket notification summary will demonstrate the substantial equivalence of the subject device, 10 Curie IR-92 Brachytherapy Source for Nucletron Afterloader device. The substantial equivalence will be based on the following features of the device:

- Indications
- Physical Size
- Radioisotope
- Radiation activity

The Alpha-Omega Services, Inc., 10 Curie Iridium 192 Source, Model CSN0010-192 device is a hermetically sealed radionuclide brachytherapy source indicated for; to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy.

The source is made of a stainless steel capsule with an outer diameter of approximately 1.1mm. A hole is drilled through the center of the capsule to a depth of the Ir 192 seed. The closed end of the capsule is welded to a 1.1 mm diameter 7 X 7 stranded stainless steel cable. On the opposite end, a solid connector is welded in the same manner to the free end of the cable A Ir 192 seed is inserted into the open end of the capsule. The Ir 192 seed is secured by welding the open end of the capsule. The post-weld length of capsule is approximately 4.5 mm in length

and overall length of the finished source cable assembly is approximately 2000 mm. These physical specifications are the same as the source for the Nucletron Microselection HDR device.

The following table compares indications statement for Alpha-Omega Services, Inc., 10 Curie IR-92 Brachytherapy Source for Nucletron Microselection HDR device and the predicate device.

10 Curie IR-92 Brachytherapy Source for Nucletron Afterloader device	IR-192 (K864210), Nucletron Microselection Predicate Device
A high specific activity radionuclide brachytherapy source to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy. Device is the active source for a Nucletron Microselection Device.	A high specific activity radionuclide brachytherapy source to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy. Device is the active source for an Nucletron Microselection

Based on the intent of the indications statement for the subject device, the Alpha-Omega Services, Inc., 10 Curie IR-92 Brachytherapy Source for Nucletron Afterloader device, is substantially equivalent to the predicate device with respect to its indications.

The following table compares the physical size, materials of construction, and the radioisotope for the subject device and predicate device.

Feature Description	10 Curie Iridium 192 Source, Model CSN0010-192 for Nucletron Microselection device	IIR-192 (K864210), Nucletron Microselection Predicate Device
Diameter	1.1 mm	1.1 mm
Length	2000 mm ± 5%	2000 mm ± 5%
Cable Type	7X7 Stranded	7X7 Stranded
Material	Stainless steel 316LVM	Stainless steel 316LVM
Seal Method	Laser / Tig Welding	Laser Welding
Radioisotope	IR – 192 Seed 3.5 mm	IR – 192 Seed 3.5 mm
Tested transfers cycles	50,000	20,000
Recommended cycles	5,000	5,000
Radioactive half life	75 days	75 days
Apparent Activity Levels	9 – 13 Ci at time of shipping	9 – 13 Ci at time of shipping

#### LIMITATIONS AND/ OR OTHER CONSIDERATIONS OF USE

1. The source cable shall be distributed in the United States to persons specifically licensed by the United States NRC or an agreement state.
2. The source cable shall be distributed internationally to users with approval from local competent authorities.
3. The source cable shall be leak tested at six (6) month intervals using techniques capable of detecting 0.005 microcuries of removable contamination.
4. Handling, storage, use, transfer and disposal will be determined by the licensing authority. The sealed source must be installed and transferred by experienced, trained and licensed personnel only using adequate handling procedures.
5. The licensee shall not cut, splice or altar the source cable in any way.
6. To be used as an active source cable for the Nucletron – Oldelft Microselectron HDR

Afterloader at existing irradiation equipment installations. The licensee shall strictly abide by all requirements of the customer's license and applicable requirements of the U.S.N.R.C., agreement state or international competent authorities in which the authorized work is performed

**External Radiation Levels**

The following are radiation dose rates for a 10 curie source

Distance (in cm)	Dose Rate (mr/hr)
1	48,000,000
25	76,800
50	19,200
100	4,800

These values are for health physics **ONLY** and not for clinical use.

Based on the dimensions of the subject device being the same as the predicate device, the body tissue contacting materials being made of a known biocompatible material, stainless steel, and both devices using IR-192 as the radionuclide, the subject device, Alpha-Omega Services, Inc., 10 Curie Iridium 192 Source, Model CSN0010-192 for use with Nucletron Microselection HDR device is substantially equivalent to the predicate device with respect to features and indications.



FEB 22 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Alpha-Omega Services, Inc.  
C/O J. Harvey Knauss  
Delphi Consulting Group  
11874 South Evelyn Circle  
Houston, TX 77071Re: K991571  
10 Curie Iridium 192 Source, Model CSN0010-192  
Dated: January 18, 2000  
Received: January 19, 2000  
Regulatory class: II  
21 CFR 892.5730/Procode: 90 KXX

Dear Mr. Knauss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number K 991571

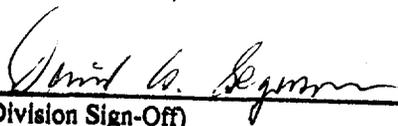
Device Name: 10 Curie Iridium 192 Source, Model CSN0010-192

Indications for use: A high specific activity radionuclide brachytherapy source to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy. Device is the active source for a Nucletron Microselection Device.

Prescription Device. Federal Law (US) restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
David W. Reymann  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K991571

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)