



**Nucletron**

RECEIVED  
REGION 1

2007 AUG -1 AM 10: 44

**Nucletron Corporation**  
8671 Robert Fulton Drive  
Columbia, MD 21046  
Tel 410-312-4100  
Fax 410-312-4199  
www.nucletron.com

Br. 3

USNRC Region 1  
Division of Nuclear Materials Safety  
475 Allendale Road  
King of Prussia, PA 19406-1415

**RE: Amendment request, License 19-28772-01, Nucletron Corporation**

03032842

Our reference:  
1ARNRC07\_07

Your reference:  
19-28772-01

Date:  
July 27, 2007

Dear Agency:

Nucletron has received a sealed source and device registry for a new afterloader—the microSelectron Model 106.990, SS&D# MD-0497-D-114-S. Therefore an amendment to Nucletron’s license is indicated. Nucletron’s scope of service for this afterloader is the same as devices currently authorized under this license. Second, the new afterlaoder uses the Nucletron Model 105.002 Ir-192 sealed source. Item 9. A. should be amended as follows:

For possession incident to the installation, maintenance, repair, and source exchange of Nucleron microSelectron HDR Model 105.999, OncoSelect PDR Model 106.999, OnocSelect HDR-3 Model 105.980 , and **microSelectron Model 106.990** remote afterloading devices.

For reference, I have enclosed a copy of the SS&D for the new device. In addition, please find enclosed a copy of the FDA 510(k) Summary of Safety and Effectiveness. The last bullet on the last page indicates the maximum source strength treatment activity as 12 Ci.

Thank-you for your attention. Any questions regarding the above matter may be directed to the undersigned at 443-545-2196.

Sincerely,

Lisa Dimmick  
Director RA/QA, RSO

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 1 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**MODEL:** microSelectron 106.990

**DISTRIBUTOR:** Nucletron Corporation  
8671 Robert Fulton Drive  
Columbia, Maryland 21046

**MANUFACTURER:** Nucletron B.V.  
Waardgelder 1  
3905 TH Veenendaal  
The NETHERLANDS

**SEALED SOURCE MODEL DESIGNATION:** Nucletron Model 105.002  
(formerly known as Mallinckrodt catalog# DRN 07736)

Mallinckrodt Medical B.V.  
Westerduinweg 3  
NL-1755 LE Petten, The Netherlands  
or  
QSA Global (Formerly  
AEA Technology)  
40 North Avenue  
Burlington, Massachusetts

**ISOTOPE:** Iridium-192

**MAXIMUM ACTIVITY:** 12 curies (444 GBq) installed. 13 curies (481 GBq) replacement source stored for decay to 12 curies at facility.

**LEAK TEST FREQUENCY:** Six (6) months

**PRINCIPAL USE:** (V) General medical use

**CUSTOM DEVICE:**  YES  NO

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 2 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**DESCRIPTION:**

The manufacturer states that the model microSelectron 106.990 afterloader is intended to provide its customers with a device that can be configured to be either in the high dose brachytherapy (HDR) mode or the pulsed dose PDR mode, where previously, separate units were required. The treatment unit is basically the same as the model OncoSelect PDR 106.999, and the model microSelectron HDR 105.999, but is equipped with a new 30-channel indexer. With interchangeable indexer cover plates and appropriate software, the treatment unit can operate with 3, 6, 18, or 30 channels in either the HDR or PDR modes. Thus, the afterloader provides a brachytherapy system for non-complex low channel patient treatments (such as single channel breast treatments) as well as complex multiple channel treatments. The device uses a single iridium-192 source, and is intended for intraluminal, interstitial, intracavitary, gynecological and superficial applicator treatments. The dose is delivered to the affected tissue by placing the source inside, adjacent to, or in close proximity to the tumor or proliferation.

The model microSelectron 106.990 is designed to be dual-purpose, i.e. HDR or PDR. The choice of HDR mode or PDR mode is controlled by software and cannot be changed by the user. The system can be configured in HDR mode only, PDR mode only, and HDR mode or PDR mode selectable. If the HDR/PDR mode selectable software is purchased, controls are in place so that neither HDR nor PDR can be used unless the source strength is optimal. If the source radiation strength is stronger than 3 Ci, the PDR mode cannot be used, and if the radiation source strength is less than 5 Ci, the HDR mode cannot be used. This is accomplished by a source strength monitor present in the system. Also, treatment plans for each HDR or PDR mode must match or the treatment plan will be rejected and the unit will not function.

The indexer contains 30 channels, but each customer software license will be for use of a certain number of channels. The front indexer cover plate determines how many channels will be available for use and software checks for those channels. If more channels than the licensed number are requested from the software, the treatment plan will be rejected, with the exception of the 30-channel license. In this case, the system will accept up to 90 channels and divide them into up to 5 sub-fractions.

The model microSelectron 106.990 consists of:

- a. Treatment Unit
- b. Treatment Control Panel (Control Box)
- c. Treatment Control Station including computer work station, printer, keyboard, pointing device, display unit, stereo audio system and TCS software
- d. Patient applicators
- e. Slave emergency stop switch
- f. Junction box
- g. Door switch
- h. Emergency/service container
- i. Treatment status indicator (optional for PDR use)
- j. Remote control unit (optional for PDR use)

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 3 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**DESCRIPTION (Continued):**

**a. Treatment Unit:** The dimensions of the treatment unit (HxWxD) are 980/1380 mm X 460mm X 800 mm (38.6/54.3 in X 18.1in. X 31.5 in) and it weighs 120 kg (264 pounds). It contains a tungsten alloy safe for the iridium-192 source, dual drive mechanisms with two stepper motors, position encoders for the source assembly and check cable, channel indexer, electrical height adjustment, electronic circuit boards, battery pack and power supply for the source and the check-cable. The treatment unit is mounted on wheels and will operate only when installed in an appropriately shielded room. See Attachments 1,2,3 & 6.

The electronic module in the treatment unit monitors the primary dwell time of programmed dwell positions and assures the accurate positioning of both the source cable and the check cable by using optical encoders which define the position of those drive cables. These optical encoders ensure that any discrepancies between the intended and actual positions of these cables will result in an immediate withdrawal of the drive cable.

The treatment unit head uses a mechanical drive, with a unique anti-kink storage mechanism and stepping motor, that eliminates backlash by stepping only in a forward direction during patient treatment. Prior to the source application a check-cable run (simulator run) is conducted to assure that the source can go through the applicator and make the correct steps. This system ensures a comparative accuracy between the simulator run and the source run of less than +/- 1 millimeter (mm) throughout the treatment.

The treatment unit is equipped with an emergency hand crank which permits the emergency retraction of the source and check cable in the event of failure of the emergency stop motor. The hand crank allows the source to be retracted only.

**b. Treatment Control Panel (Control Box):** Dimensions of the Treatment Control Panel are 135 mm X 350mm X 315 mm (5.3 in X 13.8 in X 12.4 in) and the weight is 7 kg (15.4 pounds). It contains a microprocessor control with main timer and backup timer (checked by a second microprocessor). See Attachment 3

**c. Treatment Control Station:** Dimensions of the Treatment Control Station are 330mm X 150 mm X 335mm (12.99 in X 5.91 in X 13.19 in). The user programmable functions are located in the Treatment Control Station. This console consists of a PC-based graphics terminal, which uses a Windows® – based management program. All device-programming functions are carried out at the Treatment Control Station, including default set-up parameters for the Treatment Unit and the data entry of radioactive source specification.

The control unit can store multiple standard source configurations and times, which are automatically corrected for the decay of the iridium-192 source. In the case of main power failure, the system contains a

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 4 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**DESCRIPTION (Continued):**

battery backup, which will maintain treatment data and return the source to the fully shielded position. A printer records all patient treatment data, source configurations and times. See Attachment 3.

**d. Patient Applicators:** The manufacturer provides conventional applicators for gynecological, intracavitary, intraluminal, superficial and interstitial brachytherapy along with the appropriate adapters that fit into the front of the indexing unit. All connecting tubes are individually inserted and locked. The treatment unit cannot send out a source unless an applicator is properly connected. Every treatment using a live source is preceded by a check-cable run to detect any blockage or constrictions to ascertain that the live source can move freely both out and back. If the check-cable run does not move freely out and back, the treatment run is aborted and the source remains within the safe until all obstructions are removed.

**SOURCE:**

The source, as described in SS&D Registry Sheet MD-0497-S-107-S, is constructed of iridium-192 metal (source pellet dimensions .65 millimeters (mm) diameter, 3.6 mm length), which is singly encapsulated in a stainless steel (AISI 316L) cylindrical capsule (capsule dimensions 0.9 mm diameter, 4.5 mm length). The source is at one side hemispherical and the other side welded to a metal plug and metal flexible cable. At the other end of the cable, a metal engraved tail is welded. The source cable diameter is 0.9 mm. The source tail end-piece is engraved with a unique serial number. See Attachment 4 & 5.

**LABELING:**

An adhesive-backed polyester label 65mm X 61mm (2.6 in x 2.4 in), is attached to the cover of the device below the connections on the treatment unit. This label shows the identification, operating conditions and manufacturing date of the treatment unit.

Another label made of polyester is applied to the back of the treatment head when a new source is loaded. It shows the data of the radioactive source.

See Attachment 5.

**DIAGRAMS:**

- Attachment 1. Device
- Attachment 2. Device
- Attachment 3. System Diagram
- Attachment 4. Source Diagram
- Attachment 5. Source and Device Labels
- Attachment 6. Device

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 5 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**CONDITIONS OF NORMAL USE:**

The model microSelectron 106.990 is intended for intraluminal, interstitial, intracavitary, superficial, and gynecological treatment of cancer using high dose rate radiation or it may be used as pulsed dose rate radiation therapy using a source of proper activity. The patient may be treated in a hospital, an outpatient clinic or in a private medical office. In all cases, both the patient and the treatment unit must be in a properly shielded room adequate to protect the general public and auxiliary personnel from unnecessary radiation exposure.

The system must be installed in a shielded room where the temperature does not exceed 40°C or fall below 10°C and will be operated under the direction of an authorized user. The manufacturer recommended frequency for replacing the source is 3 months. Source replacement is to be performed by a Nucletron engineer or by those specifically licensed to do so by the NRC or Agreement State. Preventive maintenance checks are performed during source exchange. On a yearly basis an extended preventive maintenance is performed.

The anticipated catastrophic condition that might occur is fire. Normally hospitals, clinics, and private offices would be constructed to meet local and national fire regulations; however, the tungsten shielding in the Treatment Unit is deemed adequate for any predicted catastrophe. Additionally, the system is designed so that the patient can be quickly disconnected and the source stored in the shield in a matter of seconds.

**PROTOTYPE TESTING:**

Prototype testing was done and complied with the following medical electrical equipment standards: IEC 60601-1 Part 1, amendments 1& 2; IEC 60601-1-2 (2001); IEC 60601-1-1-4, 1996; and IEC 60601-2-17. The device has attained KEMA certificates IEC 601 and CE. Mallinckrodt Medical B.V. has tested the sources in accordance with ISO 2919 and ISO 1677 requirements. The testing was conducted under the consultation of the Ministry of Medical Investigation and Testing (BAM) located in Berlin, Germany. The source achieved classification designation ISO/C53211.

The device was developed under ISO 9001:2000 and EN ISO 13485:2003 (KEMA certificate #55859) Quality Systems Requirements. The manufacturer indicates that the prototype was tested to conform to design specifications and that functional and safety aspects of the system were checked under normal and single fault conditions. New software for the device was tested and passed under the manufacturer's Treatment Console Software Test-Plan.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 6 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**EXTERNAL RADIATION LEVELS:**

When the main safe contains 12 Ci of iridium-192, the dose rates around the treatment unit are:

<b>Distance</b>	<b>Exposure Levels</b>
Surface	0.48 mR/hr (4.8 $\mu$ Sv/hr)
5 cm	0.27 mR/hr (2.7 $\mu$ Sv/hr)
30 cm	0.08 mR/hr (0.8 $\mu$ Sv/hr)
100 cm	0.02 mR/hr (0.2 $\mu$ Sv/hr)
100cm	Air Kerma rate is <0.15 $\mu$ Gy/hr

**QUALITY ASSURANCE AND CONTROL:**

Model microSelectron 106.990 has been tested as model 105.999 for the life of the drive motors and the metal drive cable used to transfer the source. Nucletron states that the anticipated life of these components is greater than 10 years. Factory verification of all system functions and a burn-in test is conducted prior to shipment. For permanent installations Nucletron Corporation engineers conduct quality assurance safety testing at customer sites during device installation and source exchanges. Nucletron states that installation and quality assurance safety testing following the transportation and installation of the device into a "permanent room setup" must be completed in accordance with Nucletron's instructions. Complete information on the manufacturer's quality assurance program on the microSelectron-HDR afterloading brachytherapy unit has been submitted and deemed acceptable by Maryland.

**LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:**

1. This device shall be distributed only to persons specifically licensed by the NRC or an Agreement State.
2. The Nucletron model microSelectron 106.990 remote afterloading brachytherapy device exclusively utilizes the Nucletron Corporation model 105.002 sealed source manufactured by Mallinckrodt Medical BV, Petten, Holland, and QSA Global, Inc., Burlington, MA.
3. The source shall be leak tested at intervals not to exceed six (6) months using techniques capable of detecting 0.005 microcuries of removable contamination.
4. Handling, storage, use, transfer, and disposal is to be determined by the licensing authority. because the sealed sources have high exposure rates, they must be installed and transferred only by experienced, trained and licensed personnel using adequate handling of equipment and procedures.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 7 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:, Continued**

5. The device shall be installed and initially tested for proper operations of the source exposure mechanism, safety warning component labels, external radiation levels (both source exposed and source shielded) and leak tested at appropriate intervals previously stated on page one under "leak test frequency" by trained Nucletron service personnel or persons specifically licensed by an Agreement State or the NRC. Further, the reviewer should request documentation of training/experience of the service representative who will install and service the device.
6. The device shall be installed in a shielded room that has adequate interlocks and labeling to meet the requirements of COMAR 26.12.01.01, Part D, Section D.201, Section D.601 or comparable NRC or Agreement State Regulations.
7. This registration sheet and the information contained with the references shall not be changed without the written consent of the Maryland Department of the Environment.
8. The model Nucletron microSelectron 106.990 meets Type A package requirements under testing criteria conducted on the HDR model 105.999. However, the device may only be used at appropriate locations as listed on a license issued by an Agreement State or the NRC. Following transport from one location to another, the device must be properly installed by persons specifically licensed by an Agreement State or the NRC, trained by a Nucletron Engineer and using Nucletron's "Transportation Protocol."
9. The main cable must always be kept plugged into the mains and the mains switch turned on so that the batteries will be kept charged. The manufacturer recommends that the batteries be replaced every two years.
10. Although the check-cable has been certified for more than 25,000 transfers, the manufacturer recommends that it be replaced before 5,000 transfers or one year, whichever comes first.



**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 8 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**SAFETY ANALYSIS SUMMARY:**

1. This device is designed so that the radiation source will be withdrawn into the tungsten shielding if any alarm or failure condition arises.
2. If the treatment is interrupted for any reason the source is retracted into the safe in approximately 5 seconds.
3. It is impossible to send out the radiation sources unless an applicator is correctly connected, the therapy room door is closed, and the check-cable run checks positively the condition of the applicator and the HDR system.
4. A dual timer mechanism is present. The primary timer in the Treatment Unit counts the actual dwell timing. As soon as the source leaves the safe, the secondary timer starts counting up. The trip level of the secondary timer (located in the Treatment Control panel) is set to the total treatment time plus twice the transfer time. If the source is not in the safe when the secondary timer reaches the trip level, an alarm is generated and the emergency stop circuit is activated.
5. In the event of complete failure of the system there is a hand-controlled winch, which can withdraw the source in approximately 5 seconds.
6. The door interlock switch is directly wired to the Treatment Unit. In all circumstances, if the treatment room door is opened, the radiation source will be withdrawn into the tungsten shielding.
7. Although hardware and software are designed to allow interchangeable HDR/PDR modes, a source-strength monitor built into the system prevents the inappropriate source activity from being used with each mode.

Based on our review of the information and data submitted, we conclude that the model microSelectron 106.990 designs are acceptable for licensing purposes. We conclude that this device will be expected to maintain containment integrity for both normal and accidental conditions, which might occur during routine use.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 9 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**REFERENCES:**

The following supporting documents for the model microSelectron 106.990 are hereby made part of this registry document:

1. The Nucletron Corporation application for evaluation dated May 15, 2006.
2. The FDA 510K letter dated August 17, 2006.
3. The Nucletron Corporation letters dated October 31, 2006.
4. The Nucletron Corporation letter dated November 14, 2006
5. The Nucletron Corporation letter and attachments dated January 18, 2007.
6. The Nucletron Corporation letter with attachments dated March 12, 2007.
7. The Nucletron Corporation letter with attachments dated March 13, 2007.
8. Electronic mail dated March 21, 2007
9. The Nucletron Corporation letter dated March 23, 2007
10. The Nucletron Corporation letter dated May 4, 2007
11. Electronic mail dated June 8, 2007 and June 11, 2007.

DATE: June 12, 2007 REVIEWED BY: Barbara J. Park  
Barbara J. Park

DATE: June 12, 2007 CONCURRENCE: Raymond E. Manley  
Raymond E. Manley

**ISSUING AGENCY:**

Maryland Department of the Environment  
Radiological Health Program  
1800 Washington Boulevard  
Baltimore, Maryland  
21230

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

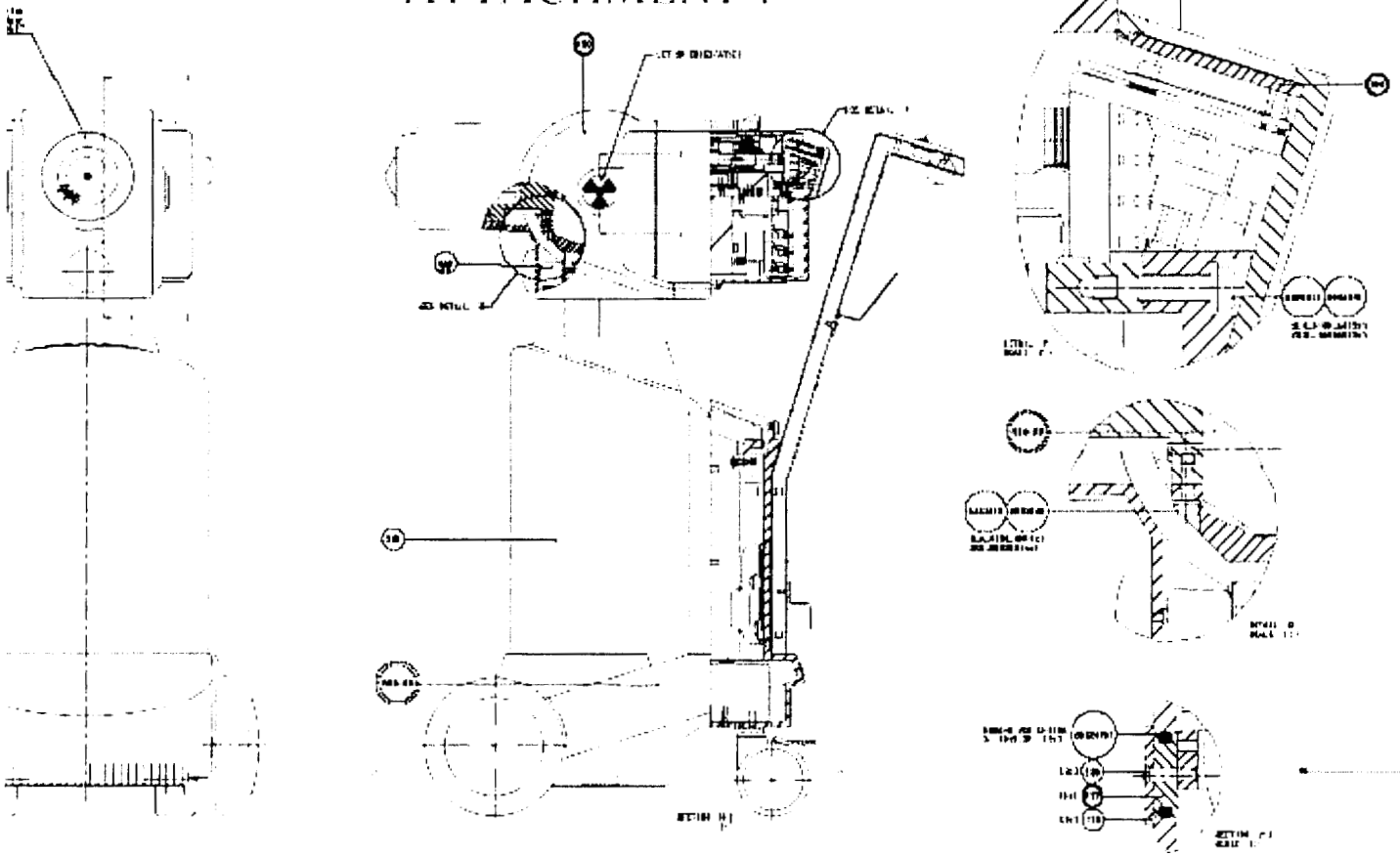
**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 10 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

ATTACHMENT 1



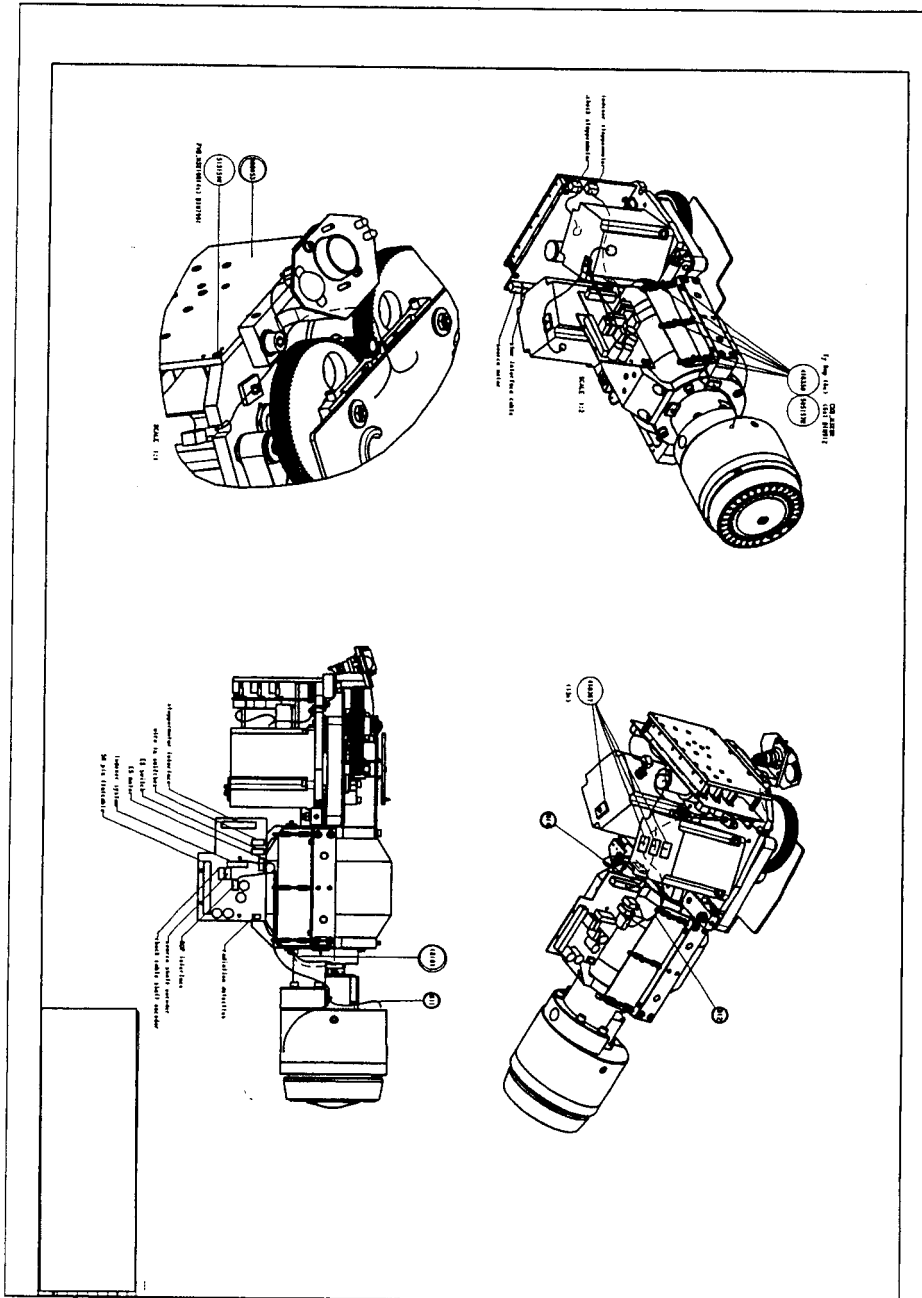
**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 11 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit



Attachment 2  
Head of Treatment  
Unit

|

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

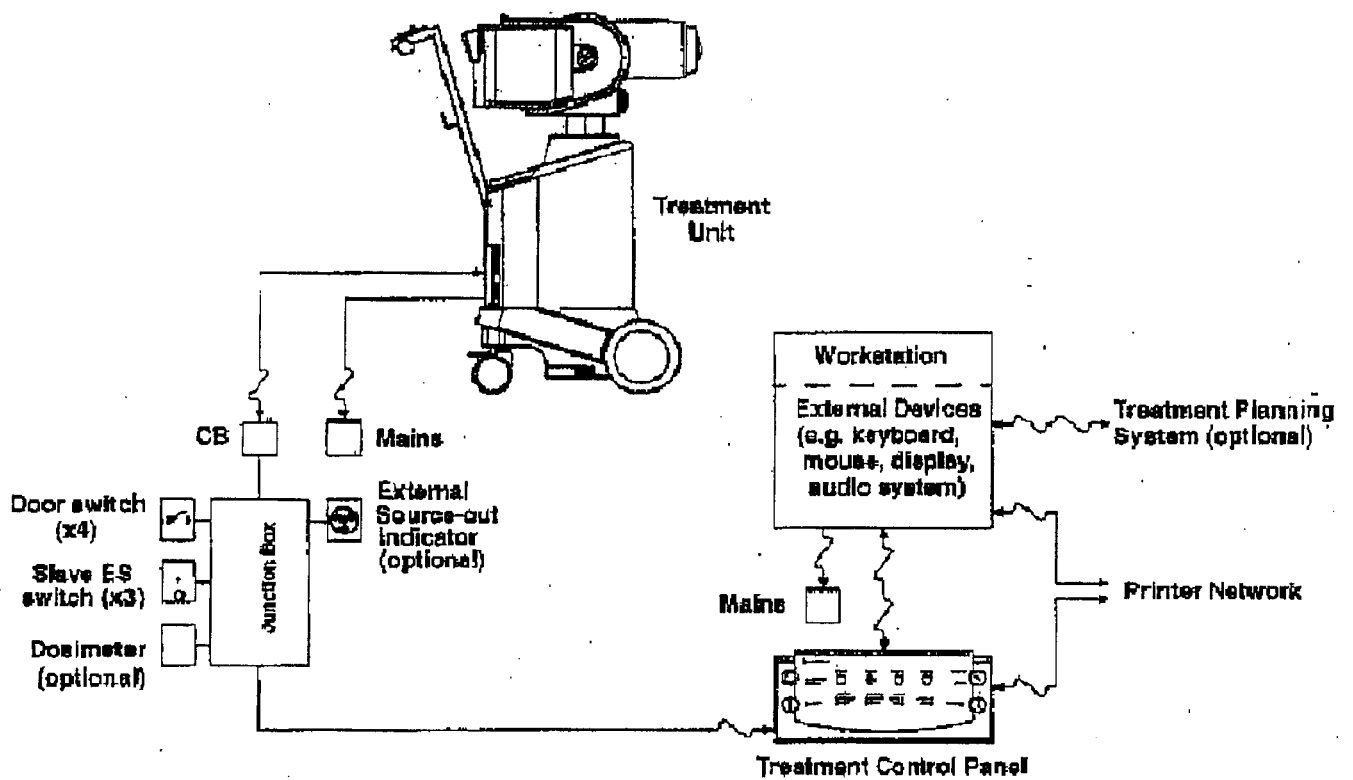
**DATE:** June 12, 2007

**Page 12 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**ATTACHMENT 3**

**Diagram of System**



**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

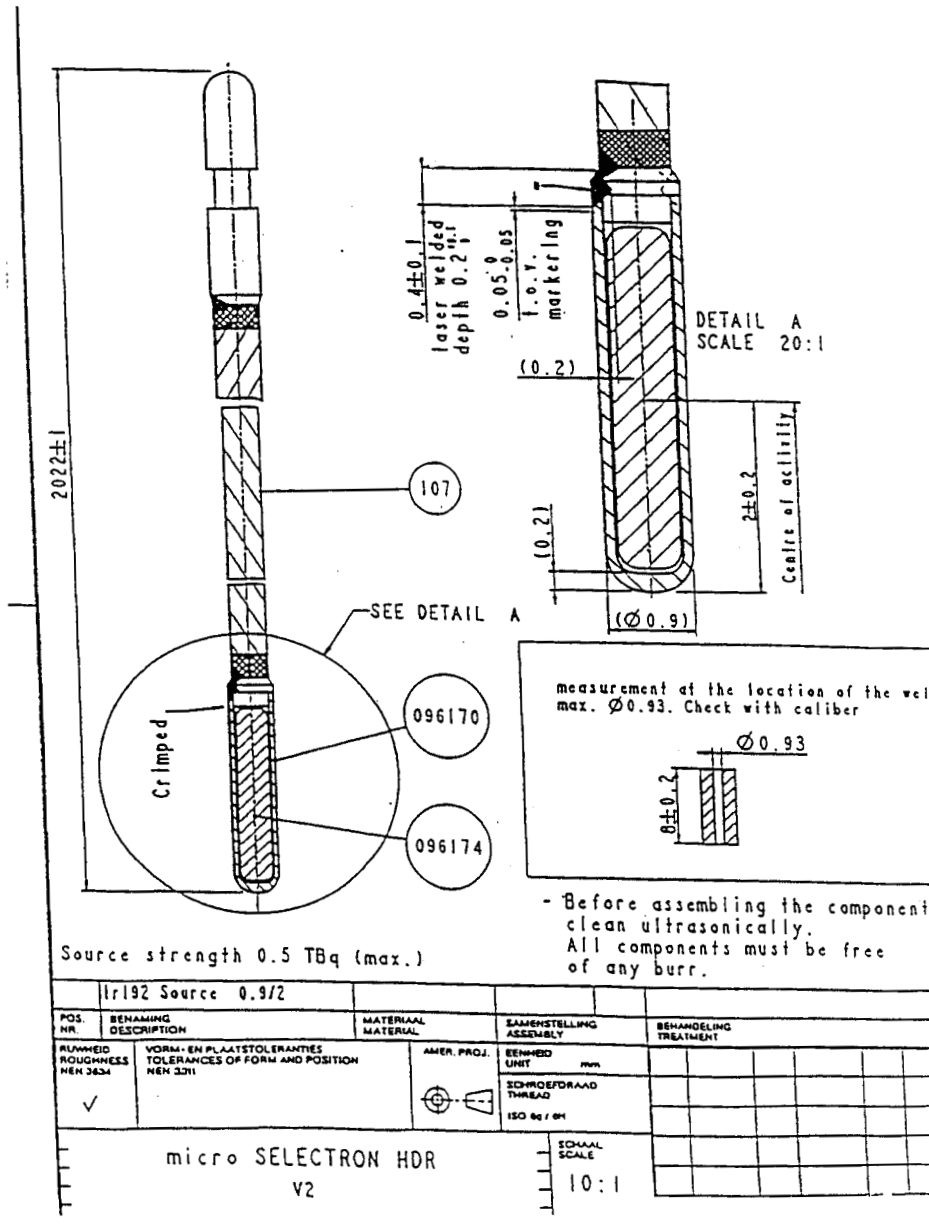
**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 13 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**ATTACHMENT 4**  
**Source Diagram**



**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**



**NO:** MD-0497-D-114-S

**DATE:** June 12, 2007

**Page 14 of 15**


**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**ATTACHMENT 5**  
**Device Labels**

 **CAUTION - RADIOACTIVE MATERIAL**  
 Nucletron

---




This device contains RADIOACTIVE MATERIAL with the following main features:

 Model Number: **REF**  
Serial Number: **SN**  
Reference Air Kerma Rate:  
Activity, Radionuclide:  
Date of Measurement:

**CE**  
0344

UNAUTHORIZED REMOVAL OF THIS LABEL IS PROHIBITED

Sticker shows source identification, strength, and calibration information. It is applied to the back of the treatment unit when a new source is loaded. Dimensions: 65 mm X 75 mm

 **Nucletron**  **CE** 0344 

Manufactured in The Netherlands, Waardgelder 1 3905 TH Veenendaal

REF: <b>106080B02-XX</b>	Part of <b>106990</b>
SN: <b>10XX3</b>	Mains Frequency (Hz): <b>50/60</b>
Weight (Kg): <b>120</b>	Power Input (W): <b>370</b>
Radionuclide: <b>Ir-192</b>	Fuse Type: <b>MDQ</b>
Max. Activity (GBq): <b>518</b>	Fuse Rating (A slow): <b>4A/250V</b>
Mains Supply (A/V): <b>4A/100-115VAC</b>	<b>2006-06-26</b>

Sticker shows electrical information, source data, and date of manufacture of treatment unit. Applied below the cable connections on the back of the treatment unit. Dimensions: 100 mm X 50 mm

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF DEVICE**

**NO:** MD-0497-D-114-S

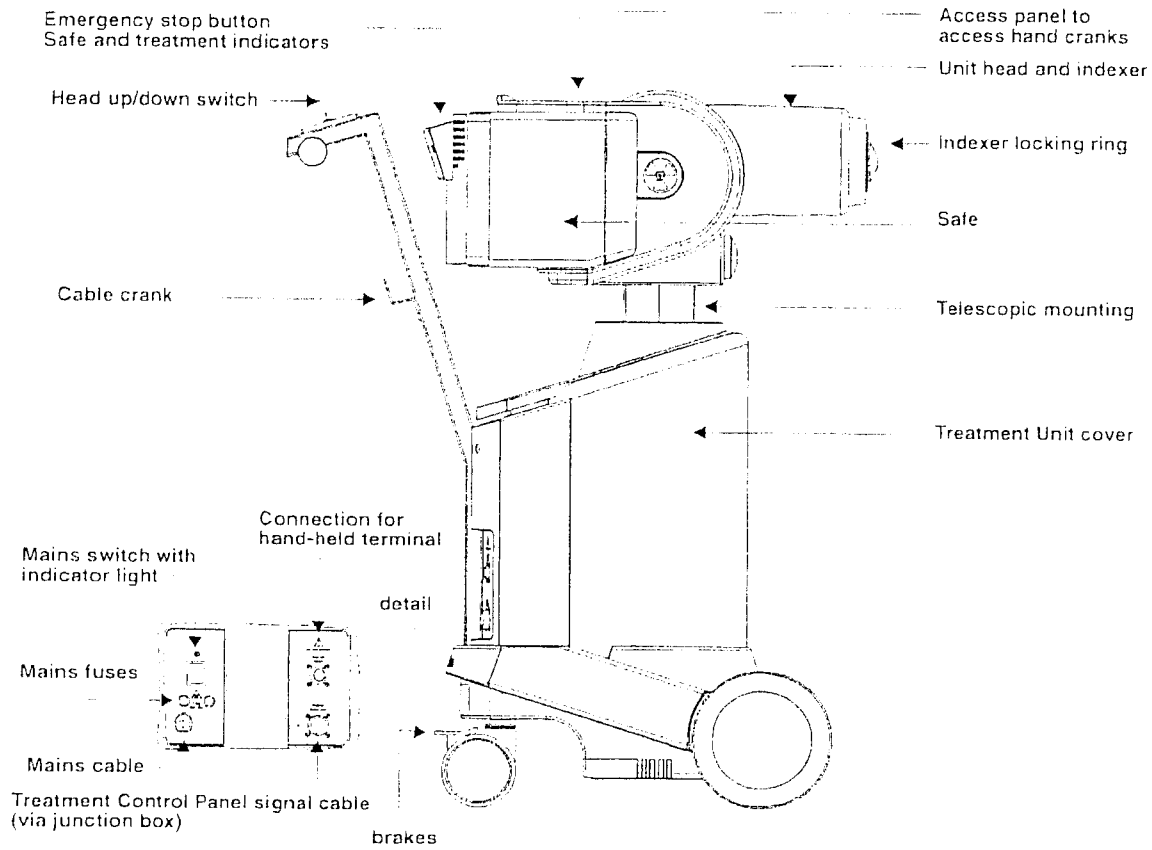
**DATE:** June 12, 2007

**Page 15 of 15**

**DEVICE TYPE:** Remote Afterloading Brachytherapy Unit

**ATTACHMENT 6**

**The Treatment Unit**







**Nucletron**

K061354

**NUCLETRON B.V.**

Waardgelder 1 3905 TH Veenendaal

P.O.Box 930 3900 AX Veenendaal

The Netherlands

Phone +31 318 557133

Fax +31 318 550485

Department of Health and Human Services  
Centre of Device and Radiological Health  
Office of Device Evaluation  
Special 510(k) section

**AUG 17 2006**

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**  
as required by section 807.92(c)

**Submitter of 510(k):**

Company name: Nucletron Corporation  
Registration number: 1121753  
Address: 8671 Robert Fulton Drive  
Columbia, MD 21046  
Phone: 410-312-4100  
Fax: 410-312-4197  
Correspondent: Lisa Dimmick  
Director Assurance & Regulatory Affairs

**Modified Device Name:**

Trade/Proprietary Name: MicroSelectron V3  
Common/Usual Name: Afterloader  
Classification Name: Remote controlled radionuclide applicator system  
Classification: 21Cfr892.5700 Class II  
Product Code JAQ

**Legally Marketed Device(s)**

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	MicroSelectron PDR	K041933

**Description:**

The MicroSelectron V3 delivers a radiation dose distribution conforming to treatment data, which is either, manually entered at the workstation or imported from a treatment planning system.

For a treatment, a source and applicator are minimally required. Treatment can be administered via up to 30 applicators connected to 30 channels in the treatment unit. The dose distributions are achieved by sequentially letting the source dwell in required positions within the applicators.

A channel has 48 possible dwell positions. Each position has a number, whereby position 1 represents the farthest possible (distal) position from the treatment unit and 48 the closest (proximal) position. The step size, which is the minimum distance between the centres of consecutive dwell positions, can be set to 2.5 mm, 5 mm, or 10 mm. All channels that are used for a given treatment have the same step size. Treatment in a channel starts at the proximal programmed dwell position. When the dwell time in the proximal position has elapsed, treatment continues in the next programmed dwell position and so on until the last dwell position has been completed; whereupon, the procedure is repeated in the next programmed channel (if applicable).

The required dose distribution can be delivered according to two principles:

- **The “high dose rate brachytherapy” principle (HDR)**, i.e. only one treatment cycle as described above is given during a treatment session. The treatment is completed when the last programmed channel is completed.
- **The “pulsed dose rate brachytherapy” principle (PDR)**, i.e. treatment cycles (pulses) are given at regular intervals (periods). A pulse includes treatment in a number of channels (determined by the user) depending on the type of application. After having delivered one pulse, the system enters a quiescent state, the duration of which is equal to the period time minus the pulse time. The period time is the elapsed time between two consecutive pulses. The second pulse starts at the end of the first period time. The whole sequence as described above for the first pulse will then be repeated. The treatment is completed when the last pulse has been delivered.

The MicroSelectron V3 consists of the following main components:

- **Treatment Unit (TU)**

The Treatment Unit contains:

- Safe for the source
- Dual drive mechanisms with two stepper motors
- Position encoders for the source assembly and the check cable, respectively
- Channel indexer
- An electrical adjustment for the height of the treatment head
- Electronic control circuit boards
- Battery pack and the power supply

- **Treatment Control Panel (TCP)**

The Treatment Control Panel (TCP) transfers treatment data from the treatment control station to the treatment unit. After the Start button is pressed at the TCP, the treatment unit will execute treatment according to this data. The TCP monitors a treatment by exchanging status messages with the treatment unit and treatment control station.

- **Treatment Control Station (TCS)**

The Treatment Control Station is a computer with a monitor and a keyboard for user programmable functions, data entry, and detailed operational information.

Once the Treatment Control Station is activated, and before any radiation treatment can be initiated, the system performs a self-test of all components which relate to safe operation.

This diagnostic program checks the system connections, memory status, backup battery status, indexer status, Control Panel indicators, internal clock and audible alarm.

For data integrity and security the system allows the definition of multiple types of users with different levels of authorization. This authorization is linked to the users password for the Treatment Control Station.

Patient and treatment data as well as applicator data is stored in the database at the treatment control station. The database stores information of treatment sessions (fractions or pulses) given a course of treatment.

- **Remote Control Unit (RCU) (optional for HDR)**  
The Remote Control Unit (RCU) is mounted outside the treatment room. After preparing a patient and programming the system, treatment can be started. Treatment can be interrupted and later resumed so that a nurse or physician can enter the treatment room and administer care to the patient. The unit also provides information about the treatment and system status.
- **Nurse Station Display (Optional)**  
The Nurse Station Display (NSD) gives staff members the possibility to remotely monitor the treatment and system status. After selecting one of up to four treatment units, the information of the selected treatment unit is shown. The nurse station display works in the same way as the remote control unit for the treatment information, error information, settings, and audible alarm.

The radiotherapy treatment planning software is not part of this 510(k) submission. Applicators and Transfer Tubes as available for microSelectron-HDR/PDR (k953946 & k041933) are also applicable for the microSelectron V3 System.

The modifications to the previously cleared device K041933 are:

- Addition of HDR functionality, part of previously cleared device K902533
- Increase of the number of channels of the indexer from 18 to 30.
- Addition of DICOM import and export functionality
- Increase of maximum source strength for treatment of patients from 40.000  $\mu\text{Gy.m}^2/\text{h}$  (10Ci) to 48.000  $\mu\text{Gy.m}^2/\text{h}$  (12Ci)

**Intended use:**

The modified device has the same intended use as the legally marketed predicate device cited:

The MicroSelectron V3 is intended to enable an operator to apply, by remote control, a radionuclide source into the body (including Interstitial, Intracavitary, Intraluminal, Bronchial, Endovascular and Intra-operative) or to the surface of the body for radiation therapy.

**Summary of technological considerations:**

MicroSelectron V3 is substantially equivalent to the cleared predicate device, microSelectron PDR, 510(k)#: K041933.



\_\_\_\_\_  
Name: Dick van Waes  
Title: Business Director Brachytherapy & Imaging  
Nucletron B.V.  
Veenendaal, The Netherlands

3 APRIL 2006  
Date

This is to acknowledge the receipt of your letter/application dated

7/27/2007, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 19-28772-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

---

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 140892.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.