



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 13 1996

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

William G. McMahon  
Senior Partner  
Normac-Will Associates  
20 Canary Court  
Guilford, CT 06437-1428

Re: K953946  
Microselectron HDR Version 2  
Dated: July 30, 1996  
Received: August 1, 1996  
Regulatory class: II  
21 CFR 892.5700/Procode: 90 JAQ

Dear Mr. McMahon:

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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 at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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**Summary of  
Safety and Effectiveness  
Information**

**1. Submitter:** Nucletron Corporation  
7080 Columbia Gateway Drive  
Columbia, MD 21046-2133

**Contact:** Stephen P. Teague  
Regulatory Affairs Director  
Phone: 410-872-4444  
FAX: 410-312-4197

**Prepared:** July 19, 1995

**2. Device Name**

microSelectron HDR version 2

**3. Predicate Device**

microSelectron HDR (K864210)

microSelectron HDR for Mobile Environment (K925956)

**4. Description:** The microSelectron HDR version 2 is an improvement over its predicate device, primarily in the areas of ergonomics and user interface. The Control Box and PC Console are designed to work with both the existing treatment unit and the new treatment unit (described below).

**4.1 Control Box:** The Treatment Control Unit of the predicate device has been redesigned to remove the user programmable functions from this electronics interface unit. This new control box retains only the key switches, Start, Interrupt, and Print push buttons from the predicate design and includes additional visual indicators of device operation. The CPU board in the Control Box was redesigned to support higher processor speeds and a processor chosen which supports the larger program size.

- 4.2 Treatment Console** The user programmable functions removed from the Control Box as described in 4.1 above, have been functionally relocated to the treatment console. This console consists of a PC based graphics terminal utilizing a commercially available window management program. All device programming functions are carried out at the treatment console, including default setup parameters for the treatment unit and the data entry for radioactive source specification. The design goal of the treatment console was to present device specific information to the user in a graphical environment consistent with the current technology in personal computers. All functions and outputs of its predicate device have been retained and more extensive (plain language) explanation for device status codes are incorporated into the software functions of the treatment console. Data structures necessary to initiate and complete a programmed treatment are stored in both the Control Box and the Treatment Unit; the treatment console merely echoes the functions being performed by the treatment unit itself.
- 4.3 Treatment Unit** The mechanics have been modified to create a more stable, movable, platform for precise positioning of the Treatment Unit adjacent to the patient. The center of gravity and stability of the shielded safe has been improved by relocating the largest mass (shielded safe) closer to the center line of the Treatment Unit. Structural rigidity between the treatment safe, the optical coupler, and the indexer is enhanced by using an annular structure rather than a linear (backbone) design. The source drive mechanism remains very similar to its predicate, with some minor improvements in the yaw angle of the source cable trajectory. The enclosure and covers for the Treatment Unit have been upgraded to a more contemporary design, in keeping with company's exterior design and esthetics philosophy.
- 4.4 Radioactive Source** The radioactive source designed for the microSelectron HDR version 2 treatment unit is functionally identical to the source contained in the predicate device. The exemplary track record of over 10,000 correct source assembly operations with the predicate source showed that minor dimensional changes to the source to enhance its suitability for clinical use would not decrease the safety of the source. To this end, the diameter of the source and its driving cable have been reduced from 1.1 mm outer <sup>to 0.9mm</sup> additionally qualified as Special Form Radioactive Material in accordance with ISO 2855. (7)
- 4.5 Optional Accessories** Optional accessories have been included in the design of this modified device including the provision of a radiation detector.
- 5. Intended Use** The intended use for the microSelectron HDR version 2 is identical to the predicate device as described in 21CFR § 892.5700 as: "intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy". This device is classified as a prescription device and will be operated only under the direct supervision of a physician in the course of the practice of medicine. There are no

additional Safety and Effectiveness issues raised in the intended use or indications for use of the microSelectron HDR version 2.

## 6. Technological Considerations

- 6.1 Mechanical** The minor mechanical improvements in the design of the microSelectron HDR version 2 treatment unit are well known and do not constitute any new technology in mechanical design. Ease of manufacturing and maintenance were two of the criteria used in developing the mechanical modifications to the predicate device. The Functional Specifications of the predicate device have not been enhanced or modified with the new mechanical design. There are no new Safety and Effectiveness issues that are raised with this new design. The increase in the amount of radioactive source shielding in the new Treatment Unit head design is a result of commercial need rather than a result on inadequacy of the predicate design. The aesthetic improvement of the Treatment Unit and Control Unit is part of Nucletron's commitment to state of the art design and manufacturing, rather than an indication that hazards or poor design existed in its parent device.
- 6.2 Electronics** The electronics design of the predicate device is approaching 9 years old, and significant development have taken place in the electronics industry since that time. The current CPU and Interface board design reflects contemporary design and manufacturing practices and will reduce the overall manufacturing cost of the electronic boards. The current device will use flash programmable memory as opposed to the predicate's EPROM memory to reduce the company's expenditure in providing additional upgrades to the installed base for the new device. Serial communications between the different electronic components of the device follow both RS232 and RS422 standards. To insure backward compatibility of the new electronics to the current predicate device Treatment Unit, a 20MA current loop serial protocol is used for this reason.
- 6.3 Software/Firmware** The functions performed by the Flash Programmable firmware in the current device duplicates the EPROM program functions of the predicate device. The use of a graphics display terminal and a commercially available Window Manager in the new device is an improvement over the command line driven liquid crystal display of the predicate device. The use of commercially available personal computers as an interface to the operator increases the amount of information that can be displayed concerning the patient, the treatment, and the function of the device during the treatment. The same information was available in the predicate device in the printed record of the treatment including the indication of any status messages and service information. s/w
- 6.4 Ergonomics and Human Factors:** Enhancement in the mechanical ergonomics have been described previously in sections 6.1 and certain human factors engineering considerations were used in section 6.3 in the design of the User Interface software. As the professionals in the field become more familiar with the use of personal computers,

the learning curve necessary to achieve competency in the operation of the device shortens.

**6.5 Backward Compatibility** A global technical consideration in the design of the microSelectron HDR version 2 was backward compatibility to the existing installed base of over 800 microSelectron HDR's, the predicate device. The Commercial Requirements Specifications for this product design addresses those issues, and the minor modifications made in the current device from its predicate have eliminated any new Safety and Effectiveness considerations during the design of this new device.

## 7.0

**7.1 Performance Standards** No performance standards have been published by the Food and Drug Administration regarding this classification of medical device. Nucletron has developed this new product under ISO 9001 Quality Systems Requirements, and additionally, has used voluntary performance standards, where appropriate, to validate the design and manufacturing capabilities of components used in the system. The radioactive source adheres to the ISO voluntary standards published for Sealed Radioactive Source design and Sealed Radioactive Source construction. An independent certification to the ISO Standards for the source has been achieved.

**7.2 Indication Statements** This device has the same Indication Statements and Indications for Use as the predicate device. Therefore, clinical tests were not required, as the predicate functional specifications were not modified.

**7.3 Validation** Successful validation to the aforementioned voluntary performance standards demonstrate that the device is safe, effective and performs as well as its predicate device and merely takes advantage of contemporary mechanical, electronically, and software design practices.