

Premarket Notification
Nucletron IBU
Date :29 August 1997

JAN 22 1998

K973848



Nucletron

NUCLETRON B.V.

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Department of Health and Human Services
Center of Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification section

FBN MKT IBU 510k
70819.4.doc
29 August 1997

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

a. Submitter of 510(k)

Company name: Nucletron Corporation
Registration # 1121753
Address: 7080 Columbia Gateway Drive
Columbia, MD 21046-2133

Contact Person:

Ralph E. Shuping
Regulatory Affairs Manager
Phone: 410-312-4100
Fax: 410-312-4197

b. Device Name:

Trade/Proprietary Name: IBU, Integrated Brachy therapy Unit
Common/Usual Name: Image-intensified fluoroscopic RT simulation system
Classification Name: Radiation therapy simulation system,
21 CFR 892.5840 Class II.

c. Legally Marketed Predicate Device(s)

Our Device is substantially equivalent to the legally marketed predicate devices cited in the table below.

Manufacturer	Device
Nucletron	Simulix-HP
Philips	Integris

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d. Description

The IBU integrated Brachy therapy imaging unit is a localization and simulation device for a radiation therapy department especially for Brachy therapy treatments. It consists of a gantry that supports an L-arm and a C-arm which can rotate isocentrically. The C-arm houses an X-Ray tube housing assembly with collimator on one side and an image intensifier with optional rotatable cassette holder. The movements of the IBU are manually driven, after the relevant electrical locks are lifted. The mobile IBU patient couch has mechanical motions which can be controlled from a hand pendant affixed to the table.

e. Intended use

The IBU is intended to be used for the visualization, localization and confirmation of the volume and size of the Brachy therapy irradiation field(s), using a fluoroscopic and/or radiographic system.

f. Summary of technological considerations

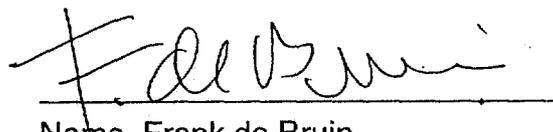
The IBU is substantially equivalent to the predicate devices. It allows visualization of volumes to be irradiated under a variety of angles. The IBU uses X-Ray imaging for diagnostic and treatment planning purposes, where by the patient is supported by a patient table which can be moved vertical, lateral and longitudinal to position the relevant anatomy in the isocenter for visualization.

To optimize the use for Brachy therapy simulation. The IBU has a mobile table operated from internal batteries, so that the patient could possibly be prepared in a separate room.

g. Standards

The IBU system is subject to Federal Performance standard 21 CFR 1020.30.

The IBU system will be manufactured in accordance with voluntary safety standards, such as UL 187 and IEC 601;



Name Frank de Bruin

Title Product Manager Simulation products

Nucletron bv

Veenendaal

Netherlands

28 Aug '97
Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 1998

Ralph Shuping, Sc.D.
Regulatory Affairs Manager
Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, MD 21046-2133

Re: K973848
IBU, Integrated Brachy Therapy Unit
Dated: October 6, 1997
Received: October 8, 1997
Regulatory class: II
21 CFR 892.5840/Procode: 90 KPQ

Dear Mr. Shuping:

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 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 requirement, 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/dsmamain.html>.

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

Enclosure

Statement of indications for use

510(k) Number (if known): K973848

Device Name: IBU (Integrated Brachytherapy Unit)

Indications for Use: The Integrated Brachytherapy Unit (IBU) is intended to be used for the visualization, localization and confirmation of the volume and size of the Brachy radiation therapy irradiation field(s), using a fluoroscopic and/or radiographic system. Localization and simulation for Brachy radiation therapy can be performed more effectively on the IBU than on a standard radiation treatment simulator. The additional L-arm allows the user to visualize under many angles easier for the operator than with the predicate device. The IBU will not be used for the simulation of external beam radiation treatments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over the Counter Use

(Optional Format 1-2-96)

David G. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973848