OCT 2 4 2005

Nucletron

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

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k): K052361

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:	Simulix-Evolution with Oncentra™ ConeBeam
Common/Usual Name:	Simulator
Classification Name:	System, Simulation, Radiation Therapy
Classification:	21Cfr892.5840 Class II
Product Code	KPQ

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	Simulix Evolution	K033470

Description:

Oncentra ConeBeam is an extension to the Nucletron Simulix Evolution system.
The Simulix Evolution is a Radiation Therapy Simulation System which is to be used in radiation therapy simulation, using a fluoroscopic and/or radiographic x-ray system for visualizing the volume to be exposed during radiation therapy and confirming the position and size of the

K052361

therapeutic irradiation field to be applied. The Simulix Evolution is previously cleared under 510(k) #k033470.
The Oncentra ConeBeam extension will give the Simulix Evolution system the capability to acquire Computer Tomography (CT) images. This is done by means of scanning the patient with a cone shaped X-ray beam. The cone shaped beam gives the possibility to acquire CT image information of a volume instead of CT image information of a single slice as with conventional fan beam CT.
The images acquired with Oncentra ConeBeam will be used for the purpose of radiation therapy planning and to check the positioning of the patient.

Intended use:

Simulix Evolution is a radiation therapy simulation system that is intended to prepare patients for radiation therapy. The Simulator emulates the geometrical positions of radiation therapy treatment machines. Using conventional radiographic and fluorographic system, patients are positioned, filmed and marked to prepare them for treatment.
The Ocentra Cone Beam CT option for the Simulix Evolution Radiotion Therapy Simulator is intended to assist the Radiation Oncologist in acquiring 3D "multi slice" planning data in patient set-ups for the purpose of radiation therapy treatment planning and patient positioning

Summary of technological considerations:

Simulix Evolution is substantially equivalent to the cleared predicate devices, Simulix Evolution, 510(k)#: K033470 and Simulix-MC CT Extension 510(k)# K932848.

Name: Frits van Krieken
Title: Business Director
Nucletron B.V.
Veenendaal, The Netherlands

27 - June 2005
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nucletron Corporation
% Ms. Jan van Lochem
Responsible Third Party Official
KEMA Quality B.V.
4377 Country Line Road
CHALFONT PA 18914

Re: K052361
Trade/Device Name: Simulix Evolution with Oncentra™ Conebeam
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: KPQ
Dated: October 12, 2005
Received: October 12, 2005

Dear Ms. Lochem:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K052361

Device Name Simulix-Evolution with Oncentra™ ConeBeam

Indications for Use

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The Simulator emulates the geometrical positions of radiation therapy treatment machines. Using conventional radiographic and fluorographic system, patients are positioned, filmed and marked to prepare them for treatment.
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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices