K041719

JUL 22 2004

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):

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:	Oncentra-VISIR
Common/Usual Name:	VISIR
Classification Name:	Medical Linear Accelerator
Classification:	21Cfr892.5050 Class II
Product Code	IYE

Legally Marketed Device(s)

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

Manufacturer	Device	510(k) #
Helax AB	Helax-VISIR	K972617

Description:

Oncentra-VISIR is a verification system designed to be a tool for supporting the process of preparing, setting up, delivering and recording radiation therapy. It will retrieve data from doseplan systems and simulators automatically or by manual input from the user. It will help administer patient sessions through the booking functionality. At each individual treatment Oncentra-VISIR will present setup data to the operator and also to the linac through a specific

interface. Actual setup will be verified. During treatment Oncentra-VISIR can monitor the progress of both Monitor Unit values and optional in vivo dosimetry. All data relevant for the given treatment can be recorded.

The main areas of modification to the previously cleared device k972617 are:

- Image Based Verification (IBV)
  This module allows the user to schedule image acquisitions on the treatment machine. Once the images are acquired they are compared to a reference image such as a DRR or digital simulator image. Automated edge detection will mark both the reference and control image and perform a comparison. A resultant displacement is translated into the treatment couch shifts required to reposition the patient correctly for the desired beam placement within the patient.
- Improved user interface – improved layout of data making it easier for the user to navigate and display the data they require. Also improved workflow requiring less clicking and password entry than before.
- Optional double signature for treatment – lets 2 therapists sign for treatment delivery
- Dynamic MLC IMRT support
- Live MLC display in treatment screens
- More flexible port filming options such as film only and orthogonal film modes
- Image acquisition (port film) scheduling
- Detailed audit trail tracks all changes to patient data with time/date/signature stamps of any edit

The software runs on a PC on a Windows NT, 2000, or XP platform.

Intended use:

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

Oncentra-VISIR is designed to be a tool for supporting the process of scheduling, preparing, setting up, delivering and recording radiation therapy.

Summary of technological considerations:

Oncentra-VISIR is substantially equivalent to the cleared predicate device, Helax-VISIR, 510(k)#: K972617.

Name: Jan-Willem Hazenoot
Title: Business Segment Manager
Nucletron B.V.
Veenendaal, The Netherlands

11/6/4
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2004

Ms. Lisa Dimmick
Director, Assurance & Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046

Re: K041719
Trade/Device Name: Oncentra-VISIR
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: June 23, 2004
Received: June 24, 2004

Dear Ms. Dimmick:

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 (PMA), 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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 K041719

Device Name Oncentra-VISIR

Indications for Use Oncentra-VISIR is designed to be a tool for supporting the process of scheduling, preparing, setting up, delivering and recording radiation therap

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,
Radiological Devices
510(k) Number K041719