K080929

APR 16 2008

Nucletron

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 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

New Device Name:

Trade/Proprietary Name:	Oncentra GYN
Common/Usual Name:	Treatment Planning System
Classification Name:	System,Planning,Radiation Therapy Treatment
Classification:	21Cfr892.5050 Class II

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	SWIFT 2.0	K031158

Description:

Oncentra GYN is a "real time" treatment planning system for brachytherapy especially meant for the treatment of gynaecological cancers. Direct 3D imaging of the treatment area gives the

physician the possibility to update the planning of the dwell positions of the radioactive source in the target volume of the patient.

The program provides a variety of plan evaluation tools to assist in generating the most optimal dose distribution, e.g. dose volume histograms, dose verification points and dose profiles. The software program provides the physician with anatomical and dosimetric information, to determine the positioning and loading of the radioactive sources, prior to radiation treatment.

The software is an adaptation of the software of the predicate device to make the software more suitable for the use with gynaecological cancers. The following features have been added for this:

- Support for applicators and needles (instead of only needles)
- 3D MRI, CT and ultra sound image import (instead of only ultra sound)
- Support of multiple target volumes (instead of only one)
- Optimisation algorithms more suitable for gynaecological treatments

The modified device is an accessory to a brachytherapy afterloader. The program consists of two modules:

- Treatment planning Software: Oncentra GYN
- Database: Smoothbase

The software runs on a Windows XP platform on the same hardware as Swift 2.0

Intended use:

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

Oncentra GYN is a software application intended for Brachytherapy Treatment Planning, for the treatment of cancer, ie. intercavitary, interstitial, intraluminal, involving radioactive sources.

Summary of technological considerations:

Oncentra GYN is substantially equivalent to the cleared predicate device, Swift 2.0, k031158.

Name: Paul van den Biggelaar
Title: Director, New Product Development
Nucletron B.V.
Veenendaal, The Netherlands

13-March 2008
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nucletron Corporation
% Mr. Jay Y. Kogoma
Technical Reviewer and Primary Contact
Intertek Testing Services NA, Inc.
2307 E Aurora Rd., Unit B7
TWINSBURG OH 44087

APR 16 2008

Re: K080929
Trade/Device Name: Oncentra GYN 1.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: March 31, 2008
Received: April 1, 2008

Dear Mr. Kogoma:

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

510(k) Number (if known) K080929

Device Name Oncentra GYN 1.0

Indications for Use Oncentra GYN 1.0 is a software application intended for Brachytherapy Treatment Planning, for the treatment of cancer, ie. intercavitary, interstitial, intraluminal, involving radioactive sources.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080929