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nomos

HOW WILL WE CHANGE RADIATION NEXT?™

Section 2 – 510(k) Summary

Summary of Safety and Effectiveness
NOMOS Motorized CRANE® II

Pursuant to Section 513(i) of the Federal Food, Drug, and Cosmetic Act

A. General Information:

Classification Name: Medical charged-particle radiation therapy system accessory: Treatment Planning System
(Sec. 892.5050)

Common/Usual Name: Radiation Therapy Treatment Planning System

Trade/Proprietary Name: CORVUS® 5.0M System

Applicant's Name and Address:

Francis X. Dobscha
Director of Quality

NOMOS Corporation
200 West Kensinger Drive
Cranberry Township, PA 16066

Phone: 724-741-8242
FAX: 724-741-0778
Email: fdobscha@nomos.com

B. Name of predicate device: NOMOS CORVUS System (K940663, K963258, K972451)

C. Classification: Class II

D. Performance Standards: None established

E. Intended Use and Device Description:

The CORVUS system is a radiation treatment planning package designed to allow medical physicists, dosimetrists, and radiation oncologists to create conformal treatment plans using photon (x-ray) external beam radiation therapy. The treatment plans generated by CORVUS are based upon

treatment machine-specific data and are intended to provide a guide to delivering external beam radiation therapy which conforms to the target volume defined by the radiation oncologist.

The CORVUS System is valid for use only with external beam photon therapy; calculations for electrons and intracavitary sources (Brachytherapy) are not supported.

The modification described in this premarket notification consists of a change to the operating system upon which the device operates. The currently-marketed CORVUS System utilizes the NextStep operating system, while the modified device runs on the Macintosh OS X (Mac OSX) operating system. This change did not modify the intended use of the device or the fundamental scientific technology of its design. Testing performed demonstrates that the modified device produces clinically equivalent results. Therefore, this change does not affect the safe and effective use of the device within its prescribed indications.

F. Summary of Substantial Equivalence

Indications for Use:

The indications for use for the CORVUS Radiation Therapy Planning System have not changed as a result of this modification.

Materials:

The materials used in the CORVUS 5.0M are equivalent to those used in the currently marketed device. The only difference is the use of computer hardware and peripherals supporting the Mac OSX operating system (versus hardware supporting the NextStep operating system).

Manufacturing:

The manufacturing processes used in the production of the CORVUS 5.0M System has not changed from that used to produce the currently-marketed predicate device. The device is manufactured at the same facility under the same process controls.

Specifications and Fundamental Scientific Technology:

The performance specifications of the CORVUS 5.0M System are the same as the currently-marketed CORVUS System. The design and the fundamental scientific technology upon which the CORVUS System operates have not changed.

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Design Controls:

The modification to the CORVUS System were developed, tested, and implemented following NOMOS Corporation's established processes for design control. NOMOS Corporation's design control processes conform to all applicable regulatory and industry requirements. A hazard analysis and testing were performed to assess the impact of the modification, which resulted in a determination that the modification does not raise any new issues of safety or efficacy for the device.

Conclusions:

Based on the above information, and on NOMOS Corporation's commitment to provide safe, reliable, and effective products, NOMOS considers the CORVUS 5.0M Radiation Therapy Planning System to be substantially equivalent to the currently-marketed CORVUS System.

Note:

Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be legally marketed according to FDA regulations and is not relevant evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, *". . . a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without premarket approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits."* 42 Fed. Reg. 42,520 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Ms. Francis X. Dobscha
VP, Quality and Regulatory Affairs
NOMOS Corporation
200 West Kensinger Drive
CRANBERRY TOWNSHIP PA 16066

Re: K032209
Trade/Device Name: CORVUS Radiation Therapy Planning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: July 14, 2003
Received: July 22, 2003

Dear Ms. Dobscha:

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 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

510(k) Number: Not Assigned K032209

Device Name: **CORVUS® 5.0M Radiation Therapy Planning System**

Indications for Use:

The indications for use for the CORVUS Radiation Therapy Planning System have not changed as a result of this modification.

The CORVUS system is a radiation treatment planning package designed to allow medical physicists, dosimetrists, and radiation oncologists to create conformal treatment plans using photon (x-ray) external beam radiation therapy. The treatment plans generated by CORVUS are based upon treatment machine-specific data and are intended to provide a guide to delivering external beam radiation therapy which conforms to the target volume defined by the radiation oncologist.

The CORVUS System is valid for use only with external beam photon therapy; calculations for electrons and intracavitary sources (Brachytherapy) are not supported.

(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
510(k) Number K032209