SEP 3 1999

K991966

Section 2 - Summary & Certification

1. 510(k) Summary

Summary of Safety and Effectiveness
The NOMOS® CRANE II™

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

A. General Information:

Classification Name: Powered Radiation Therapy Patient Support Assembly Accessory

Common/Usual Name: Caliper

Trade/Proprietary Name: NOMOS® CRANE II

Applicant's Name and Address: William O. Chishko
Director, Quality and Regulatory Affairs
NOMOS Corporation (NOMOS)
2591 Wexford Bayne Road (Suite 400)
Sewickley, PA 15143
Phone: 724-934-8200
FAX: 724-934-5488

B. Name of predicate device(s): NOMOS CRANE (K941927)

C. Classification: Powered Radiation Therapy (RT) Patient Support Assembly Accessories are Class II (21 CFR 892.5770).

D. Performance Standards: The FDA has established No applicable performance standards under section 514 of the Food, Drug and Cosmetic Act.

E. Intended Use and Device Description:

Intended Use: The NOMOS CRANE II is intended to be used as an accessory to powered, radiation therapy patient support assemblies. The CRANE II verifies and describes, via a set of X, Y and Z coordinates, the set-up of the couch/patient prior to treatment.

Device Description: The NOMOS CRANE II is an accessory to powered radiation therapy patient support assemblies. The NOMOS CRANE II attaches to the stationary base of the treatment table through a permanently installed interface plate

and clamps to the accessory rails of the moveable couch top. A treatment table foot brake is also installed, if not already part of the treatment table, to further stabilize the stationary base. The treatment table foot brake is typically an accessory that can be purchased from the treatment table original equipment manufacturer (OEM). In cases where the foot brake is not an OEM accessory, one will be adapted or custom designed for the application. The CRANE II can be removed from the treatment table with only the interface plate remaining on the stationary base of the treatment table.

The CRANE II uses precision ball screw drive positioning tables, one for the Y-axis and one for the X-axis, to position the couch top relative to the stationary base of the treatment table. The positioning tables are operated using a small hand crank.

Each axis of the CRANE II incorporates a battery powered digital scale that measures the movement of the positioning table and therefore, the movement of the couch top itself. The digital scale may be set to display the value in inches, however, the operator's manual instructs the user to set the digital scale to display millimeters With the CRANE II attached, the couch top can be manipulated over a range of 12 inches (304.8 mm) in both the Y and X axis with no impedance on the couches range of travel in the Z-axis.

F. Summary of Substantial Equivalence

Indications: The indications for the NOMOS CRANE II are the same as those for the predicate NOMOS CRANE; i.e., to display the prescribed distance of patient indexing.

Design: The design of the NOMOS CRANE II is similar in concept to the relevant features of predicate NOMOS CRANE except that the table stabilization is provided by a foot brake incorporated in the RT Table or installed by NOMOS or other contractor.

Materials: The materials used in the NOMOS CRANE II are similar to those used in the relevant feature of the predicate NOMOS CRANE.

Manufacturing: The manufacturing processes used in the NOMOS CRANE II are similar to those used in the manufacture of the predicate NOMOS CRANE.

Specifications: The specifications of the NOMOS CRANE II are the same as the predicate NOMOS CRANE except that the claimed accuracy is $\pm$ 0.1 mm vs. $\pm$ 3 mm for the NOMOS CRANE. NOMOS has validated the more precise accuracy claims and has included the validation data in Appendix 5 of this submission.

Conclusions: The indications, design, materials, manufacturing, and specifications of the NOMOS CRANE II do not raise any new issues relating to safety and effectiveness.

NOMOS thus considers the NOMOS CRANE II equivalent to the predicate NOMOS CRANE.

Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or reclassification and is not to be interpreted as an admission or used as 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 whatever 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

SEP 3 1999

William O. Chishko
Director, Quality & Regulatory Affairs
NOMOS Corporation
2591 Wexford Bayne Road
Sewickley, PA 15143

Re: K991966
NOMOS CRANE II
Dated: June 1, 1999
Received: June 10, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Chishko:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):
Device Name: **NOMOS® CRANE II**
Indications for Use:

The NOMOS® CRANE II is intended to be used as an accessory to powered, radiation therapy patient support assemblies. The NOMOS CRANE II verifies and describes, via a set of X, Y and Z coordinates, the set-up of the couch/patient prior to treatment.

(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) (Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991966