FEB 6 1998

Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act

K974310

November 14, 1997

1. General Provisions

Common/Usual Name:	Collimator
Proprietary Name	NOMOS Slit Collimator (BEAK™)
Applicant Name and Address	NOMOS Corporation 2591 Wexford Bayne Road Sewickley, PA 15143

2. Name of Predicate Devices[1]

- Radionics Software Applications, Inc. (RSA) X-Knife (K953482);
- RSA Linac-Based Stereotactic Radiosurgery System (K923522).
- Blocks prepared at the user site using the Heustis Compu-Cutter (K 940145).

3. Classification

The NOMOS Slit Collimator is an accessory to a medical charged-particle radiation therapy system or a beam shaping block:

- RS collimators are reviewed by the Center for Devices and Radiological Health's Division of Reproductive, Abdominal, ENT and Radiological Devices Classification Panel and were placed into Class II 21CFR 892.5050 (IYE).

- Beam shaping blocks are reviewed by the Center for Devices and Radiological Health's Division of Reproductive, Abdominal, ENT and Radiological Devices Classification Panel and were placed into Class II 21CFR 892.5710 (IXI).

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[1] 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 pre-market 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 be lawfully marketed without pre-market 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 seg. (1977).

4. Performance Standards

Performance standards for this type of device have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description

The NOMOS Slit Collimator (BEAK™) is intended for use in Radiosurgery/Radiation Therapy to secondarily collimate the width of the radiation beam after it passes through the MIMiC® (K940412) Multileaf Intensity Modulating Collimator. Several sizes of collimators will be provided with a slit width, at isocenter, ranging from 1 mm to 8 mm.

Description: The Slit Collimator (BEAK) is tungsten block whose purpose is to provide secondary collimation for the radiation beam exiting from the NOMOS MIMiC (K940412). The MIMiC has the capability of delivering treatment slices whose width is either 8 mm or 16 mm. The Slit collimator, by providing secondary collimation of the 8 mm beam, allows slices to be delivered that are 1 - 8 mm in thickness without the need to modify the control mechanisms built into the MIMiC that ensure that leaf (vane) movement is functioning correctly. In this sense, the Slit Collimator serves the same purpose as the secondary collimators provided with radiosurgical systems or the secondary collimators, commonly called blocks, that are used with radiation therapy linear accelerators.

6. Biocompatibility

Not applicable.

7. Summary of Substantial Equivalence

The design similarities between this device and the predicate devices are:

- The NOMOS Slit Collimator has the same basic design as the RS collimator (RDA X-Knife (K953482)) except for the slit vs. circulator shape of the collimator;
- The NOMOS Slit Collimator has the same intended use as the predicate RS collimator or blocks; i.e., to collimate or shape the output beam produced by a linear accelerator or LINAC for RT/RS procedures;
- The NOMOS Slit Collimator uses the same radiodense material; i.e., tungsten.
- The design differences between the NOMOS Slit Collimator and the RS Collimator and blocks is primarily in the shape of the aperture (i.e., the Slit Collimator is rectangular shaped while the RS collimator is circular and the blocks may be slit or irregular shape.

The NOMOS Slit Collimator is similar in design, materials, intended use, indications, contraindications and performance specifications to previously

cleared devices. By introducing the NOMOS Slit Collimator, therefore, no **new** issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 6 1998

Marvin L. Sussan, Ph.D.
Nomos Corporation
2591 Wexford Bayne Road
Sewickley, PA 15143

Re: K974310
Nomos Slit Collimator (BEAK)
Dated: November 14, 1997
Received: November 17, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Dr. Sussan:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
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 BEAK™ Slit Collimator

Indications for Use:

The NOMOS Slit Collimator (BEAK™) is intended for use in Radiosurgery/Radiation Therapy to secondarily collimate the width of the radiation beam after it passes through the MIMiC® Multileaf Intensity Modulating Collimator (K940412). Several sizes of collimators will be provided with a slit width, at isocenter, ranging from 1 mm to 8 mm.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The Counter Use ___
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974310