DEC 21 1999

K993359

Section 2
510(k) Summary of Safety and Effectiveness
RAPTOR® Treatment Planning System

Pursuant to Section 513(I) of the Federal food, Drug, and Cosmetic Act and 21 CFR 807.92:

(a) (1) Submitter's name:	**NOMOS Corporation**
(a) (1) Submitter's address:	**2591 Wexford Bayne Road Sewickley, PA 15143**
(a) (1) Submitter's telephone number:	**(724) 934-8200**
(a) (1) Contact person:	**William O. Chishko Director, Quality and Regulatory Affairs**
(a) (1) Date summary was prepared:	**October 4, 1999**
(a) (2) Trade or proprietary name:	**RAPTOR® Treatment Planning System**
(a) (2) Common or usual name:	**Radiation Therapy Treatment Planning System**
(a) (2) Classification name:	**Accelerator, Linear, Medical, Accessory 90 IYE [21 CFR 892.5050]**
(a) (3) Predicate device:	**Radiation Oncology Computer Systems, *Treatment Planning System* K982791** **Theratronics, *TheraPlan Plus* K970236** **NOMOS Corporation, *PEACOCK® System* K963258**

(a) (4) Device description:

The RAPTOR Treatment Planning System is a collection of software modules that execute known and documented algorithms to produce radiation dose estimations. All data is user controlled and is a table look-up format. Information is presented graphically on CRT screens and hardcopy reports. Various models are available based on the specific features desired by the customer (e.g., asymmetric jaws, electron pencil beam calculations, etc.) to best meet their clinical needs. The software is designed to run on a PC platform utilizing the Microsoft® Windows NT® operating system. The RAPTOR Treatment Planning System includes modules for the development of instructions and controls for multileaf collimators. It is designed to upgradable in both hardware and software features. All dates are four digit numbers so the system is year 2000 compliant.

(a) (5) Intended use:

The RAPTOR® Radiation Treatment Planning System is intended to be used by radiation oncology professionals for clinical review and judgement of radiation treatment plans and dose

estimates based on computation, output and displays. The goal of the system is to produce consistent results using well-documented algorithms. It will provide outputs for radiation delivery equipment including documented and released multileaf collimators [MLCs] for planning, optimization, delivery and reporting of treatments. The device provides output data in the form of displays, hardcopy prints and / or plots, set-up instructions and other control information to guide the physician and / or other competent health care professional in selecting the optimum patient treatment plan.

(a) (6) Technological characteristics:

The RAPTOR® Treatment Planning System is designed to run on the Microsoft Windows NT operating system the same as the ROCS Treatment Planning System [K982791]. The RAPTOR® Treatment Planning System uses the same software architecture and hardware platform as the ROCS Treatment Planning System. It was developed and tested using Quality system design control and product release procedures.

It differs in that a module for calculating the effects of multileaf collimators and providing instructions for their control like those found in PEACOCK® System is added.

(b) (1) Non-clinical tests submitted:

The RAPTOR® Treatment Planning System was developed and tested using the design controls set forth in the NOMOS Corporation Quality System. It has a product specification, which was used as the basis for the development of verification and validation plans, tests and acceptance criteria. A rigorous hazard analysis also was performed, which includes mitigation for each identified hazard. Design reviews were conducted at appropriate stages of development.

(b) (3) Test Conclusions:

Validation and verification testing of the RAPTOR® Treatment Planning System demonstrate that the software is safe and effective. Test completion shows that the device performs and is equivalent to the predicate systems for those features for which this submission is being made as well as overall performance. Product release also is made in accordance with established NOMOS Corporation Quality System Procedures after all tests are completed, reviewed and meet acceptance criteria and regulatory requirements.

NOTE

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1999

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

Re: K993359
RAPTOR Treatment Planning System
Dated: October 4, 1999
Received: October 6, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Chishko:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The Federal Register notice exempting your device type was published on January 21, 1998, Vol. 63, No. 13, page 3142, and was effective immediately. Therefore, manufacturers of devices falling within the above classification regulation are now exempt from the premarket notification requirements of the Act if they comply with the classification criteria. Your device's product code, classification regulation and regulatory class are shown above. When listing your device with the Food and Drug Administration, please use this product code. We suggest that you review this above referenced regulation since it may grant other exemptions from certain general controls of the Act.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review the section entitled "Limitations on Exemptions" in the above referenced Federal Register notice to determine whether or not your new device(s) meets the exemption criteria. This Federal Register notice may be accessed on the World Wide Web at "www.fda.gov/cdrh/modact/frclass2.html" or obtained by facsimile from the Division of Small Manufacturers Assistance's Facts On Demand at (800) 899-0381 or (301) 827-0111. The order number for this notice is #394.

If you have any questions regarding this letter, please contact the Premarket Notification Staff at (301) 594-1190 or the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

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

510(k) Number [if known]: K993359
Device Name: **RAPTOR® Treatment Planning System**
Indication for Use:

The RAPTOR® Treatment Planning System is used to generate computation, display, evaluation and output radiation dose estimates for clinical review and judgement prior to treating the patient. It uses well-documented algorithms to provide output data in the form of displays, hardcopy prints, plots and treatment instructions to guide the radiation oncology professional and / or physician to select the optimum treatment plan. The MLC module is used to generate plans and instructions for documented and released multileaf collimators. The RAPTOR® Treatment Planning System is intended to be used by a competent health professional such as a radiation oncologist, medical physicist, radiation therapist, or dosimetrist.

[PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE AS NEEDED]

Concurrence of the CDRH
Office of Device Evaluation [ODE]

Prescription Use ✓ OR Over the Counter Use____
(Per 21 CFR 801.109) (Optional Format , 2 January 1996

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993359