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Tab 2
510(k) Summary of Safety and Effectiveness
PEREGRINE™ Radiation Therapy Dose Calculation 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 26, 1999**
(a) (2) Trade or proprietary name:	**PEREGRINE™ Radiation Therapy Dose Calculation System**
(a) (2) Common or usual name:	**Radiation Therapy Dose Calculation System**
(a) (2) Classification name:	**Accelerator, Linear, Medical, Accessory 90 IYE [21 CFR 892.5050]**
(a) (3) Predicate device:	**ADAC Laboratories *Pinnacle³ 3D Treatment Planning Throughput*** **K926008**
(a) (4) Device description:	

The PEREGRINE Radiation Therapy Dose Calculation System is a 3-D Monte Carlo radiation transport system designed to provide accurate dose calculations for radiation therapy treatment planning. PEREGRINE combines Monte Carlo-based modeling of the accelerator beam production system, Monte Carlo simulation of treatment-specific beam modifiers and Monte Carlo transport in the patient to provide a robust and accurate representation of the radiation source, beam modifiers and heterogeneities in the patient. PEREGRINE has been designed to provide highly accurate, high resolution radiation dose calculations rapidly on economical, commercially available computer microprocessors and to be easily integrated with commercial radiation treatment planning systems. In order to ensure its accuracy, PEREGRINE has been verified against a comprehensive set of clinical measurements designed to stress the physics algorithms for a full range of clinically relevant materials, densities and beam energies for open, blocked, wedged and compensated fields incident on both simple phantoms and phantoms with a variety of surface and sub-surface heterogeneities.

(a) (5) Intended use:

The PEREGRINE Radiation Therapy Dose Calculation System is intended to be used for radiation therapy in conjunction with a Radiation Treatment Planning system to calculate dose distributions. It is to be used by the physician and/or other competent health professionals for clinical review and judgement of radiation treatment plans. The goal of the system is to produce consistent highly accurate dose calculations using the Monte Carlo algorithms.

(a) (6) Technological characteristics:

The PEREGRINE Radiation Therapy Dose Calculation System is designed to interface to radiation treatment planning systems using industry standard protocols. It was developed and tested using Quality system design control and product release procedures.

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

The PEREGRINE Radiation Therapy Dose Calculation System was developed and tested using the design controls set forth in the NOMOS Corporation Quality System. Some portions of the system were developed and tested at Lawrence Livermore National Laboratories using design controls set forth in Lawrence Livermore National Laboratories Quality System. This system was audited by NOMOS and found to be compliant with the requirements of the NOMOS Quality System as well as the regulatory requirements of the FDA Quality System Regulations and EC Medical Device Directive. 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. Verification and validation tests were completed in accordance with the test plans. They prove that the PEREGRINE Radiation Therapy Dose Calculation System meets the design criteria and user needs. Design reviews were conducted at appropriate stages of development.

(b) (3) Test Conclusions:

Validation and verification testing of the PEREGRINE Radiation Therapy Dose Calculation System demonstrate that the software is safe and effective. Test completion shows that the device performs and is substantially equivalent to the predicate system 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Francis X. Dobscha
Director of Quality and Regulatory Affairs
NOMOS Corporation
2591 Wexford Bayne Road
Sewickley, PA 15143

Re: K993675
Peregrine™ Radiation Therapy Dose Calculation System
Dated: July 11, 2000
Received: July 13, 2000
Regulatory Class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Mr. Dobscha:

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) 594-4639. 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 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number [if known]: K993675
Device Name: **PEREGRINE™ Radiation Therapy Dose Calculation System**
Indication for Use:

The PEREGRINE™ Radiation Therapy Dose Calculation System is used in conjunction with a radiation treatment planning system to provide the dose distribution for radiation therapy treatments employing radiation sources and associated beam modifiers for clinical review and judgement prior to treating the patient. The PEREGRINE™ Radiation Therapy Dose Calculation 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

David A. Legorreta
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993675