

K981424
July 17, 1998

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

April 17, 1998

1. General Provisions

<u>Common/Usual Name</u>	Patient Positioning System, Ultrasound
<u>Proprietary Name</u>	BAT TM Ultrasound Localization and Positioning System
<u>Applicant Name and Address</u>	NOMOS Corporation 2591 Wexford Bayne Road Sewickley, PA 15143

2. Names of Predicate Devices¹

<u>Product</u>	<u>Clearance Number</u>	<u>Clearance Date</u>
Ausonics OPUS 2 Realtime Ultrasound Scanner	K945957	4/15/96
MMS TherpacPLUS 6.6 B3DTUI (K930506) Treatment Planning System	K930506	8/29/94
CP Bio-Medical Corp. PatPos Compact Laser Positioning Device	K930295	5/21/93
Mayfield/ACCISS Stereotactic Workstation	K955397	4/30/96

3. Classification

This device is classified as a class II device according to 21 CFR 892 sections 5050, 5750, 5780, or 5840.

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 seq. (1977).

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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

BAT is intended for use in external beam Radiation Therapy (RT)/Radiosurgery (RS) to locate internal anatomy that moves relative to external or bony landmarks, so as to position that anatomy correctly for the delivery of conformal radiation.

BAT permits its user to align the isocenter crosshairs, structure contours or calculated dose (the latter 2 imported from a treatment planning system) with perpendicular ultrasound images acquired at treatment time. The BAT system then guides couch motion to achieve the desired patient alignment with the treatment beam. Additional ultrasound images can be taken to confirm proper positioning.

6. Biocompatibility

All BAT components contacting the patient are 510(k) cleared (ultrasound probe: K945957; ultrasound gel: K802146 or equivalent). These components are made for diagnostic ultrasound using materials that have a long history of safe use for those applications. Their use in conjunction with BAT does not raise any new issues related to safety or effectiveness.

7. Summary of Substantial Equivalence

This device is similar in design, construction, materials, intended use and performance characteristics to the predicate devices. No new issues of safety or effectiveness are introduced by using this device.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 1998

Marvin L. Sussman, Ph.D.
Vice President, Product Assurance
NOMOS Corporation
2591 Wexford Bayne Road
Sewickley, PA 15143

Re: K981424
BAT Positioning and Localization System
Dated: April 17, 1998
Received: April 20, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Dr. Sussman:

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 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,

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: BAT™ Ultrasound Localization and Positioning System

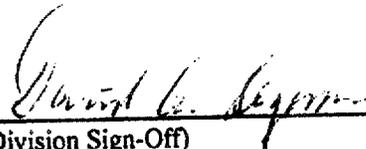
Indications for Use: BAT can be used for the positioning of all patients that are prescribed external beam radiation treatments to organs which are readily identifiable on ultrasound images.

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

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 K951474

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