K972451
JAN. 22, 1998

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

June 27, 1997

1. General Provisions

Common/Usual Name	Image Correlation System
Proprietary Name	Coregistration function
Applicant Name and Address	NOMOS Corporation 2591 Wexford Bayne Road Sewickley, PA 15143

2. Name of Predicate Devices

ImageFusion – Radionics Software Applications (RSA), Inc. (K960071)[1]

3. Classification

CORVUS™ (Cleared as PEACOCK® Plan (K940663) is classified as class II devices according to 21 CFR 882.5050 (90 IYE). These devices are reviewed by the Radiological Devices Panel of the Reproductive, Abdominal, Ear, Nose, and Throat and Radiological Division of the Office of Device Evaluation.

The predicate Radionics ImageFusion Software is unclassified by FDA but was grouped in LLZ with no CFR designation by the Radiological Devices Division.

4. Performance Standards

Performance standards for treatment planning systems have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

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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).

5. Intended Use and Device Description

The Coregistration function is intended for use as part of an RT planning system (such as CORVUS) in procedures which could benefit from the ability to correlate between multiple image sets regardless of the modality used for scanning. In addition this function may be used to coregister earlier patient scans without a localization system.

The Coregistration function enables the use of complementary image data while maintaining the geometric accuracy and tissue density information from the CT.

6. Biocompatibility

Not applicable.

7. Summary of Substantial Equivalence

This device is similar in design, intended use and performance characteristics to the predicate devices. Testing shows that the device meets similar performance specifications as those for the predicate devices. No new issues of safety or effectiveness are introduced by using this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 1998

Marvin L. Sussman, Ph.D.
Vice President
Product Assurance
NOMOS Corporation
2591 Wexford Bayne Road Suite 400
Sewickley, PA 15143

Re: K972451
Coregistration Function
Dated: October 27, 1997
Received: October 28, 1997
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 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,

William 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: Coregistration

Indications for Use:

The Coregistration function is intended for use as part of an RT planning system (such as CORVUS) in procedures which could benefit from the ability to correlate between multiple image sets regardless of the modality used for scanning. In addition this function may be used to coregister earlier patient scans without a localization system.

The Coregistration function enables the use of complementary image data while maintaining the geometric accuracy and tissue density information from the CT.

(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 K972451