PHILIPS

Philips Medical Systems

K971489

P.O. Box 10000, 5680 DA Best, The Netherlands

Department of Health and Human Services
Center for Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification section.

JUL - 3 1997

TQM XRD
XDB 087-970165/RR/rr

1997.03.17

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

for

PHILIPS MULTI DIAGNOST 4 - ROTATIONAL ANGIOGRAPHY OPTION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The undersigned certifies that the 510(k) Pre-Market notification for the above referenced product contains adequate information and data to enable CDRH to determine substantial equivalence.

This information and data is summarized as follows:

1. The MD 4 Rotational Angiography option is subject to Federal Performance Standards, defined in 21CFR - part 1000;

2. The MD 4 Rotational Angiography option will be manufactured in accordance with voluntary safety standards, such as UL 187 ;

3. The information for Users contains comprehensive information to insure safe and effective use;

4. Past experience with substantially equivalent predicate devices has shown our device to be safe and effective when used as directed in the Information for Users.
   Refer to the Philips Integris V3000 Rotational Angio function, cleared under K923813

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
710 Bridgeport Avenue
Shelton , CT 06484-0917

Re: K971489
Rotational Angiography Option for
Philips MultiDIAGNOST 4
Dated: April 21, 1997
Received: April 23, 1997
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

JUL - 3 1997

Dear Mr. Altman:

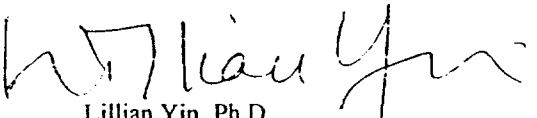
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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, 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): ~~Unknown~~ K971489

Device Name : **Rotational Angiography Option for Philips MultiDIAGNOST 4**

Indications For Use :

The Rotational Angiography Option for Philips MultiDIAGNOST 4 is indicated for use in Angiographic diagnostic imaging examinations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971489

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109

(Optional Format 1-2-96)