PHILIPS

PHILIPS

K977348.2

Philips Medical Systems

510(k) Summary of Safety and Effectiveness

NOV 1

Company name:	Philips Medical Systems North America Company
Address:	710 Bridgeport Avenue Shelton, CT 06484
Contact person:	P. Altman
Telephone number:	203-926-7031
Prepared:	September 10, 1997
Device name:	**Philips INTEGRIS V5000 FAMILY**
Classification name:	Angiographic X-ray system, 21 CFR 892.1600 Class II (90 IZI)
Common/Usual name:	Angiographic x-ray system
Predicate Device(s):	Philips Integris V3000 (Re.: K910370)

Intended use:

The Philips INTEGRIS V5000 and BV5000 system family is intended for use in dedicated vascular and neurovascular applications, including diagnostic and interventional procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography as well as PTA's stent placements, embolisations, and thrombolysis. The systems are also intended for use in mixed cardiac/vascular/neuro applications and also non vascular interventions.

System description:

The family of Philips INTEGRIS V5000 and BV5000 systems are angiographic X ray systems for vascular, neurovascular and cardiovascular procedures, as well as non-vascular procedures. The monoplane Philips INTEGRIS V5000 system features a ceiling suspended CESAR C-arm stand that can be configured with a 12" or 15" Image Intensifier. In the biplane system, Philips INTEGRIS BV5000, a floor mounted CESAR C-arm stand is combined with a ceiling suspended double C-Arc (LARC). The Floor-mounted CESAR C-arm stand can be configured with a 12" or 15" Image Intensifier, the LARC always features a 12" Image Intensifier.

Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917
Tel: (203) 926-7674
Fax: (203) 929-6099

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1997

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917

Re: K973482
Philips Integris V5000 and BV5000
Dated: September 12, 1997
Received: September 15, 1997
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

Dear Mr. Altman:

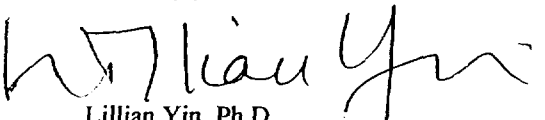
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Device Name : **Philips Integris V5000 and BV5000 Systems**

Indications For Use :

The **Philips INTEGRIS V5000 and BV5000** system family is intended for use in dedicated vascular and neurovascular applications, including diagnostic and interventional procedures.

This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography as well as PTA's stent placements, embolisations, and thrombolysis. The systems are also intended for use in mixed cardiac/vascular/neuro applications and also non vascular interventions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973482

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109

(Optional Format 1-2-96)