

I. General Information

Classification Name: Angiographic x-ray system
Common/Usual Name: digital imaging system
Device Trade Name: Digital Imaging System (BSR)
Classification: Class II Medical Device

Intended Use: Intended for use in acquiring diagnostic quality images during cardiac, angiographic, vascular and neurovascular applications.

Establishment Name and Address: Siemens Medical Systems, Inc.
Nuclear Medicine Group
2501 North Barrington Road
Hoffman Estates, IL 60195-5203

Establishment Registration Number: 1423253 (Owner/Operator 9010023)
Performance Standard: None established under Section 514 of the Food, Drug and Cosmetic Act

II Safety and Effectiveness Information Supporting the Substantial Equivalence Determination**General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use. It includes indications for use and cautions. This information assures safe and effective use of the device.

Substantial Equivalence:

The Digital Imaging System (BSR), is substantially equivalent to currently marketed Siemens Medical Systems, Inc. Polytron TOP (K933664) and Phillips Integris Series (K984545).

Contact:

Robert W. Callahan
Manager of Regulatory Affairs
Siemens Medical Systems, Inc.
Nuclear Medicine Group
2501 North Barrington Road
Hoffman Estates, IL 60195-5203
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SEP 1 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert W. Callahan
Manager of Regulatory Affairs
Siemens Medical Systems, Inc.
2501 North Barrington Road
Hoffman Estates, IL 60195-5203

Re: K991922
Digital Imaging System (BSR)
Dated: June 4, 1999
Received: June 7, 1999
Regulatory Class: II (two)
Product Code: 90 IZI
21 CFR 892.1600

Dear Mr. Callahan:

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) 594-4613. 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) K991922

Device Name: Digital Imaging System (BSR)

Indication for Use:

The Digital Imaging Systems (BSR), are intended for use in acquiring diagnostic quality images during cardiac, angiographic, vascular and neurovascular applications.

PLEASE DO NOT WRITE BELOW THIS LINE
Concurrence of the CDRH, Office of Device Evaluation (ODE)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991922

Prescription Use
(Per 21 CFR 801.109)

Or

Over-The-Counter Use

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