

SEP - 7 2001

Special 510(k)
Imager II Angiographic Catheter
May 29, 2001

Summary of Safety and Effectiveness

General Provisions**Trade Name:** Imager™ II Angiographic Catheter**Classification Name:** Diagnostic Intravascular Catheter

Name of Predicate DevicesNightHawk Angiographic Catheter

ClassificationClass II

Performance StandardsPerformance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act

Intended Use and Device Description

The IMAGER™II Angiographic Catheters are designed to provide a pathway for delivering contrast media to selected sites in the vascular system. The IMAGER™II Angiographic Catheters are sterile, single-use diagnostic intravascular catheters and are available in a variety of flush and selective shapes with lengths of 40 cm, 65 cm, 90cm and 100 cm. The distal segment of the catheter is radiopaque to aid in visualization of the device under fluoroscopy.

Biocompatibility

The IMAGER™II Angiographic Catheters have been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use.

Summary of Substantial Equivalence

The IMAGER™II Angiographic Catheters have been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.



SEP - 7 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jodi Lynn Greenizen
Boston Scientific/Medi-Tech®
One Boston Scientific Place
Natick, MA 01760-1537

Re: K011664
IMAGER™ II Angiographic Catheters
Regulation Number: 870.1200
Regulatory Class: II (two)
Product Code: DQO
Dated: August 13, 2001
Received: August 14, 2001

Dear Ms. Greenizen:

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

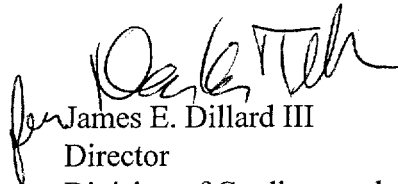
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have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4586. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k)
Number
(if known)

Unknown

K011664

Device Name:

IMAGER™II Angiographic Catheters

Indications
for Use

The IMAGER™II Angiographic Catheters are indicated for use to provide a pathway for delivering contrast media to selected sites in the vascular system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Use
(Per 21 CFR 801.109)

OR

Over-The Counter
(Optional Format 1-2-96)

W. O. K. T. L.
Division of Cardiovascular & Respiratory Devices
510(k) Number K011664