K991231

MAY 24 1999

510(k) Summary

Hitachi Versiflex

Common/Classification Name: System, 21 CFR 892.1650, 892.1650

Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, OH 44087-2371

330-425-1313, 330-425-1410 (FAX)
Contact: John T. Newland, Prepared: March 19, 1999

A. LEGALLY MARKETED PREDICATE DEVICES

The **Hitachi VERSIFLEX** is substantially equivalent to the presently marketed Hitachi SX-VA30 Fluoroscopy/Angiography System (as cleared in K964990). The **VERSIFLEX** is manufactured by Hitachi Medical Corporation, Hitachi Hagoromo Building, 1-2-10 Uchi-Kanda, Chiyoda-Ku, Tokyo, 101, Japan. This 510(k) is submitted because the **VERSIFLEX** is a new device.

B. DEVICE DESCRIPTION

The **Hitachi VERSIFLEX** is a new product. The **VERSIFLEX** is a multi-directional fluoroscopic/angiographic and radiographic system, incorporating a C-arm supporting base and an integrated patient tilting table into one system. With this system it is possible to carry out fluoroscopic/angiographic or radiographic examinations from various angles, and in combination with an X-ray generating unit and an image processing system, it can be used for multi-purpose examinations.

C. INTENDED USE

The **VERSIFLEX** is intended to visualize anatomical structures by converting a pattern of x-radiation into an image through electronic amplification and recording, and, when used with injection of contrast medium, to visualize the heart or blood vessels.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Hitachi VERSIFLEX** has an indications for use statement that is

almost identical to that of the legally marketed predicate device. That is, it has the same intended use. The **Hitachi VERSIFLEX** has the "same technological characteristics" as the predicate devices, and these characteristics are sufficiently precise to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the **Hitachi VERSIFLEX** are the same as for the SX-VA30 C-Arm Floroscopic/Angiographic System.

F. TESTING

The **VERSIFLEX** is being tested to UL-2601 and will not be marketed until the testing reaches a successful conclusion.

G. CONCLUSIONS

Hitachi Medical Systems America has demonstrated that the **Hitachi VERSIFLEX** is substantially equivalent to the Hitachi SX-VA30 Fluoroscopy/Angiography System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 1999

Hitachi Medical Corporation
C/O Whit Athey, Ph.D.
Senior Consultant
C.L. Macintosh & Associates, Inc.
Medical & Regulatory Affairs Services
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K991231
Hitachi Versiflex
Dated: April 12, 1999
Received: April 12, 1999
Regulatory Class: II
21 CFR 892.1600/Procode: 90 IZI
21 CFR 892.1650/Procode: 90 JAA

Dear Mr. Athey:

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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Hitachi SF-VA200 X-Ray Fluoroscopy and Radiography System

Indications For Use:

The **SF-VA200** is intended to visualize anatomical structures by converting a pattern of x-radiation into an image through electronic amplification and recording, and, when used with injection of contrast medium, to visualize the heart or blood vessels.

(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 K991231

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