JUL - 2 2002

510(k) Summary

K021314

1. Submitter Information:

1.1. Submitter:

Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, OH 44087
Phone: (847) 463-2001
FAX: (847) 463-2011

1.2. **Manufacturing Facility**:

Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, OH 44087
Phone: (847) 463-2001
FAX: (847) 463-2011

1.3. **Contact:**

Robert H. McCarthy

1.4. Date: April 19, 2002

2. Device Name

2.1.	***Classification Name:***	PACS (21CFR Section 892.2050)
	Classification Number:	90LLZ
2.2.	***Trade/Proprietary Name:***	SCEPTRE-VS
2.3.	***Predicate Device:***	Nuclear-Diagnostics HERMES workstation, K 002782

3. Device Description

3.1. Function

The SCEPTRE-VS is a workstation/server consisting of a computer, keyboard, mouse, monitor, network interface ;optional storage device(s) such as magneto-optical disk ,compact disk amd magnetic tape; and optional film digitizer.
The computer workstation is PC based utilizing the latest Intel Pentium technology. The operating system is Windows 2000/XP.
The Sceptre-VS workstation is used to store, process, view and print diagnostic medical images from diagnostic imaging systems conforming to DICOM 3.0 including x-ray, MRI, CT, PET, Nuclear Medicine and

Ultrasound. Several proprietary image formats can also be accomodated.The optional Fusion 7D fusion module can be used for fusion of 2 modalities such as CT/PET, MRI/PET to provide cross-modality comparison.

4. Device Intended Use:

4.1. The intended use of the SCEPTRE-VS is to review, process, film and store multi-modality images acquired from other diagnostic imaging systems or workstations.

5. Device Technological Characteristics:

5.1. The characteristics of the Sceptre-VS workstation compare substantially with the Nuclear-Diagnostics Hermes Workstation predicate device, in both materials used, technology applied, and functional methodology. Differences of note do not affect safety and effectiveness of the device, intended use, or application methods. The device operates in a manner substantially equivalent to other cleared devices in this category, and performs as well as the predicate Hermes.

5.2. Safety

The SCEPTRE-VS is a non-invasive device. It has been designed to comply with applicable safety standards and the applicable sections of 21CFR.
The results of the hazard analysis indicate that the device is of minor level of concern as defined in the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Mr. Robert H. M°Carthy
Technical Director
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K021314
Trade/Device Name: Sceptre-VS Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 24, 2002
Received: April 25, 2002

Dear Mr. M°Carthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K02 1314

Device Name: Sceptre-VS

Indications for Use:

The intended use of the Sceptre-VS is to review, process, film and store multi-modality images acquired from other diagnostic imaging systems or workstations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lippman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K02/314

Prescription Use √ OR Over-the-Counter Use _____