

K972229

510(k) Summary

for

OCT 16 1997

ImageView™ Coronary Angiography Display and Review System

1. Applicant

HeartWare, Inc.
Laurston Court
Durham, NC 27712

Contact Person: Laurence A. Spero
Telephone: 919-471-6613

Date Prepared: June 12, 1997

2. Device Name

Proprietary Name: ImageView™ Coronary Angiography Display and Review System

Common Name: Cardiac Image Review Software

Classification Name: Accessory to Angiographic X-Ray Systems

Classification Status: Class II

3. Predicate Devices

- DICOMview™
Heartlab, Inc.
K954479
- Kodak Digital Science Cardiac Review Station CRS 2000
Jamieson Film Co.
K960043

4. Device Description

The ImageView™ Coronary Angiography Display and Review System is an angiographic image review software program. It is provided on a 3½-inch 1.44 MB floppy disk. The disk contains the installation program, ImageView™ executable files, a Readme file and Dynamic Link Library files. ImageView™ is designed to read and display angiographic images which have been stored using the DICOM 3.0 format for medical images.

5. Intended Use

The ImageView™ Coronary Angiography Display and Review System is a computer program which can be used to view the results of an X-ray cardiac angiography procedure on a personal computer workstation. The digital image record of the X-ray exposures made during a catheterization procedure can be retrieved from a compact disk (CD) and displayed on a computer workstation monitor. ImageView™ also allows the user to change the appearance of the images and export selected frames to other programs for printing and further manipulation.

6. Technological Characteristics

The ImageView™ Coronary Angiography Display and Review System is intended for the same general purposes as the predicate devices identified above. The functional performance of all of the devices is comparable. The ImageView™ System and the predicate devices employ graphical user interfaces to perform the necessary functions required to display and review a DICOM image record. All systems access images from a DICOM CD and can display images either directly from the CD or by loading the images into RAM for improved performance.



OCT 16 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cynthia A. Sinclair
Senior Staff Consultant
Heartware, Inc.
c/o Medical Device Consultants, Inc.
49 Plain St.
North Attleboro, MA 02760

Re: K972229
ImageView Coronary Angiography Display and
Review System (Cardiac Device Accessory)
Dated: September 25, 1997
Received: September 26, 1997
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

Dear Ms. Sinclair:

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): _____

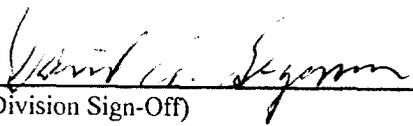
Device Name: ImageView™ Coronary Angiography Display and Review System

Indications For Use:

The ImageView™ Coronary Angiography Display and Review System is a computer program which can be used to view the results of an X-ray cardiac angiography procedure on a personal computer workstation. The digital image record of the X-ray exposures made during a catheterization procedure can be retrieved from a compact disk (CD) and displayed on a computer workstation monitor. ImageView™ also allows the user to change the appearance of the images and export selected frames to other programs for printing and further manipulation.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number 1972229

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)