

OCT 7 1999

510(K) Summary

Date Prepared: June 7, 1999
Name of Contact Person: Ralph J. Flatau
Address: InfiMed, Inc
121 Metropolitan Drive
Liverpool NY 13088
Phone: (315)453-4545 x224
Fax: (315)453-4550

Device trade name: Cardiovascular Work Station (CWS) 5000 and CWS 3000
Common name: Digital Imaging System
Classification Name: Picture Archival and Communications System (as per 892.2050)

Predicate substantially equivalent devices:

Kodak Digital Science Cardiac Viewer (K974086)
Kodak Digital Science Cardiac Archive and Review System (K960043)

Device Description:

The InfiMed Cardiovascular Workstation CWS 5000 provides digital **acquisition and review** of DICOM images. The CWS 5000 will acquire ACC/NEMA DICOM images or real-time, high resolution 1024 line analog secondary image capture. The CWS 5000 output is ACC/NEMA DICOM. Patient images may be written to CD-R media according to the ACC/NEMA DICOM standards for permanent archive and/or patient interchange. In addition, the CWS 5000 provides DICOM image **review** including multi-modality imaging to support diagnosis and therapy of cardiovascular patients. MR, CT, Nuclear, Ultrasound and CR imaging may be compared to cath lab cardiac and peripheral vascular angiography to enhance clinical analysis and save physician time. Images may be formatted for multi-modality display and printing on laser cameras. The CWS 5000 is compatible with standard network technology and is conformant to DICOM standards.

The InfiMed Cardiovascular Workstation CWS 3000 provides DICOM image **review** including multi-modality imaging to support diagnosis and therapy of cardiovascular patients. Patient studies may be reviewed in real-time or slow motion using a knob on a dedicated cardiology remote control (optional). MR, CT, Nuclear, Ultrasound and CR imaging may be compared to cath lab cardiac and peripheral vascular angiography to enhance clinical analysis and save physician time. Images may be formatted for multi-modality display and printing on laser cameras. The CWS 3000 is compatible with standard network technology and is conformant to DICOM standards. In addition, the CWS 3000 is available with a high speed direct digital connection to the InfiMed Gold One for filmless operation including DICOM review, CD-R generation and networking.

Intended Use:

The InfiMed Cardiovascular Workstation provides digital acquisition and review of cardiac images. The system can acquire images from a variety of sources (including through DICOM transfer, real-time high resolution 1024 line analog secondary image capture and high speed direct digital connection). Patient images may be stored locally (on hard drive, written to CD-R media and / or networks) or stored to permanent archive, using the DICOM standards. In addition, the Cardiovascular Workstation provides image review of patient studies in real-time or slow motion, as well as processing capability. Review functionality also includes multi-modality imaging to support diagnosis and therapy of cardiovascular patients. MR, CT, Nuclear, Ultrasound and CR imaging may be compared to cath lab cardiac and peripheral vascular angiography to enhance clinical analysis and save physician time. Images may be formatted for multi-modality display and printing on laser cameras.

Predicate device specifications comparison:

| | Cardiovascular workstation | Kodak Digital Science Cardiac Viewer (K974086) | Kodak Digital Science Cardiac Archive and Review System (K960043) |
|--|--|---|--|
| Archiving data format | DICOM 3.0 | DICOM 3.0 | DICOM 3.0 |
| Image viewing speed (maximum) | 60 frames / second | 60 frames / second | 24 frames / second |
| Display image resolution | 1280 x 1024 pixels (standard) 256 bit color or monochromatic | 800 x 600 pixel (minimum) 256 bit color or monochromatic | 1280 x 1024 pixels (standard) monochromatic |
| Compression concept and standards | JPEG Lossless Compression | JPEG Lossless Compression | JPEG Lossless and Lossy Compression |
| “Window / level / zoom / edge features | Yes | Yes | Yes |
| Forward / Reverse / Still capability | Yes | Yes | Yes |
| Hardcopy Capability | Yes, DICOM print printers | Yes - windows based printers | Yes - windows based printers |
| User Input | Keyboard and Cardiology Specific Remote Control, DICOM worklists | Keyboard and mouse | Keyboard and Cardiology Specific Remote Control |
| Image acquisition | Multi modality DICOM receive, | DICOM receive - XA and Ultrasound | DICOM receive - XA class only |

| | | | |
|------------------------------|---|------|------|
| | of video stream, direct digital connection | | |
| Outputs | DICOM send , ACC / NEMA DICOM CD-R writing | None | None |
| Measurement capability | Quantitative Coronary Analysis and Left Ventricular Analysis | None | None |
| Multi run dynamic viewing | Yes | No | No |

Performance Data: Not required for the determination of substantial equivalence of this device.

Conclusions drawn from comparison:

The CWS performs the same functions in the same environment as the predicate devices. There are some new features offered with the CWS, but these are built on the same basic functionality offered by the CWS and the predicate devices and raise no new questions of efficacy or substantial risk.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ralph J. Flatau
Quality Assurance Manager
Infimed, Inc.
121 Metropolitan Drive
Liverpool, NY 13088Re: K992575
CWS 3000/5000 Cardiovascular Work Station
Dated: July 30, 1999
Received: August 2, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Flatau:

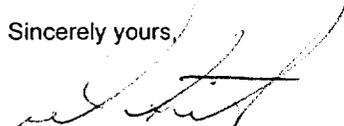
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

Indication for Use

510(K) Number (if known): _____

Device Name: CWS 3000 / 5000 Cardiovascular Work Station

Indication for Use:

The InfiMed Cardiovascular Workstation provides digital acquisition and review of cardiac images. The system can acquire images from a variety of sources (including through DICOM transfer, real-time high resolution 1024 line analog secondary image capture and high speed direct digital connection). Patient images may be stored locally (on hard drive, written to CD-R media and / or networks) or stored to permanent archive, using the DICOM standards. In addition, the Cardiovascular Workstation provides image review of patient studies in real-time or slow motion, as well as processing and analysis capability. Review functionality also includes multi-modality imaging to support diagnosis and therapy of cardiovascular patients. MR, CT, Nuclear, Ultrasound and CR imaging may be compared to cath lab cardiac and peripheral vascular angiography to enhance clinical analysis and save physician time. Images may be formatted for multi-modality display and printing on laser cameras.

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Concurrence of CDRH, Office of Device Evaluation (DOE)

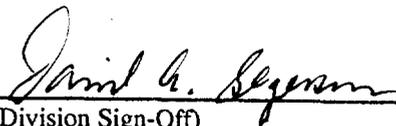
Prescription Use _____

Or

Over the counter Use

Per 21 CFR 801.109

(Optional format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992575