

DEC 8 1998

**SUMMARY OF SAFETY AND EFFECTIVENESS
for
SPECIAL 510(k) MODIFICATION SUBMISSION**

DEVICE CLASSIFICATION NAME: PACS System (Picture Archiving and Communications System)
REGULATION NUMBER: 892.2050
COMMON/USUAL NAME: PACS System (Picture Archiving and Communications System)
TRADE/PROPRIETARY NAME: PACSPlus, version 2.0
PREVIOUS 510(k) DEVICE NAME: MaxiView Radiology Workstation
PREVIOUS 510(k) DEVICE NUMBER: K930500
ESTABLISHMENT LICENSE NO.: 1933179

REASON FOR SPECIAL 510(k) SUBMISSION:

The predicate device has been modified to incorporate changes in technology. A comparison chart is included as a part of the Special 510(k) submission.

SYSTEM DESCRIPTION:

"Dynamic PACSPlus Version 2.0 is an information-enabled PACS (Picture Archiving and Communication System) that integrates all information from the RIS with images from PACS. Image capture is available from most imaging modalities using DICOM interfaces and selected non-DICOM interfaces. PACSPlus InfoBroker Servers are used as gateways that capture the DICOM images, reconcile the DICOM information with order information from the RIS, and provide access to additional exam and patient information including results. The PACSPlus Image and Information Server stores, indexes, and distributes images and information. Images can be viewed through the web-based Dynamic WebSight viewer. Exams can be accessed by patient identifiers, location, or by physician. The entire imaging exam history is shown (film and digital) to allow the viewer to select any results or available digital images."

(source: Product Fact Sheet, Dynamic Healthcare Technologies, Inc.)

INTENDED USE:

Dynamic PACSPlus is a powerful image management tool designed for use by technologists, radiologists and other healthcare professionals. **Dynamic PACSPlus** is fully compatible with the RADPlus and Maxifile RIS as well as other Hospital and Radiology Information Systems. The product provides client/server-based multimedia results viewing and distribution.

SAFETY STATEMENT:

Dynamic Healthcare Technologies, Inc.'s PACSPlus product, version 2.0, is a set of software applications and interfaces that do not directly come into contact with the patient. Further, as specified in our Users' Guide, this product is intended for use by trained professionals only, who utilize their education and experience to evaluate and review the data obtained and make a decision using that professional judgement. We believe this software product to be a safe and effective device to be on the market.

CONTACT INFORMATION:

Dynamic Healthcare Technologies, Inc.
 615 Crescent Executive Center, Fifth Floor
 Lake Mary, FL 32746-2109



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Karen White
Senior Consultant, Regulatory Affairs
Dynamic Healthcare Technologies, Inc.
615 Crescent Executive Court
Fifth Floor
Lake Mary, FL 32746Re: K984023
Dynamic PACSPLUS™ Version 2.0
Dated: November 12, 1998
Received: November 12, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. White:

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 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,

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): K984023

Device Name: Dynamic PACSPlus, version 2.0

Indications for Use Statement

Dynamic Healthcare Technologies' PACSPlus, version 2.0, is indicated for use by radiology professionals to capture, store, distribute and display radiological images and information over local and Wide Area Networks. The only editing of the images is via the wavelet lossy compression feature, using the Pegasus PICtools™ Medical Compression toolkit, a 510(k)-cleared medical device product (K#982146).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984023

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____