

SEP 14 1998

K982146

**510 (k) Summary  
as required by 807.92 9 (c)  
for PICTools Medical Compression Toolkit  
Prepared June 8, 1998**

Submitted by: Pegasus Imaging Corporation  
4010 Boy Scout Boulevard  
Suite 400  
Tampa, Florida 33607-5799  
telephone: 813-875-7575

Contact: Andrew Hudson  
Director of Business Development

Device Trade Name: **PICTools Medical Compression Toolkit**

Common Name: Medical Image Compression Software Toolkit

Classification: Picture Archiving and Communications Systems were reviewed by the Radiology Panel and are classified in Class II per 21 CFR 892.2050. Image compression devices that label all lossily compressed images as such are being considered by the agency for exemption from premarket notification requirements [510(k)].

Predicate Devices: **Access Radiology (Framework) K972925 and WinRad Teleradiology System (K936179).**

Description of Devices:

**PICTools Medical** is a software development kit written in 'C' for software developers to write applications interfaces to integrate particular image data compression algorithms into their medical imaging applications. It provides an array of high performance image compression libraries intended for use by developers of medical devices in the fields of radiology, cardiology, digital dentistry, ultrasound, and telepathology.

Intended Use of Device:

**PICTools Medical Compression Toolkit** is intended to be used by software developers in the development of applications for the compression of the data in digital medical images.

Substantial Equivalence to Predicate Device:

The wavelet compression algorithm in **PICTools Medical Compression Toolkit** is substantially equivalent to that in **Access Radiology (Framewave)** (K972925). The JPEG compression algorithms in **PICTools Medical Compression Toolkit** are substantially wquivalent to those in WinRad Teleradiology System (K936179). The clinical functionalities of the three devices are compared below.

	Wavelet image compression	JPEG image compression
<b>PICTools Medical Compression Toolkit</b>	X	X
<b>Access Radiology (Framewave) (K972925)</b>	X	



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Andrew Hudson  
Director of Corporate Development  
Pegasus Imaging Corporation  
4010 Boy Scout Blvd., Suite 400  
Tampa, FL 33607Re: K982146  
PICTools Medical Compression Toolkit  
Dated: June 10, 1998  
Received: June 17, 1998  
Regulatory class: II  
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Hudson:

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): K982146

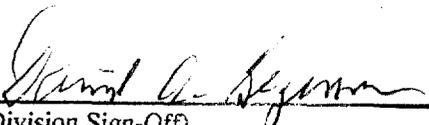
Device Name: PICTools Medical Compression Toolkit

Indications For Use:

**PICTools Medical Compression Toolkit** is intended to be used by software developers in the development of applications for the compression of the data in digital medical images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K982146

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use