OCT 6 1998

K982563

1 510(k) Summary for Ultrapro 98

1.1 General Information

1.1.1 Name and Address of Manufacturer

RamSoft Inc.
37 Bankview Circle
Toronto, ON M9W 6S6, CANADA
Tel: (416) 674-1347
Fax: (416) 674-7147
Email: ram@ramsoft.on.ca
Contact Person: Naganatha S Ramanathan

FDA/CDRH/ODE/DHC
23 JUL 98 11 37

1.1.2 Establishment Registration Number

9006410

1.1.3 Common and Proprietary names of Device

Trade or Proprietary Name: Ultrapro™
Common Name: Picture Archiving and Communication System

1.1.4 Class

Systems, digital image communications - Class I 892.2020 LMD

1.2 Substantially Equivalent Devices

ALI UltraPACS (K925965/A) with ALI comPACS data compression module (K963610)
Manufactured by: ALI Technologies, Inc

CEMAX-ICON Archive Manager 2.0 and Autorad modules (K955092)
Manufactured by: CEMAX-ICON Inc.

1.3 Device Description

Ultrapro is a tool for a medical imaging practice. It can acquire medical images from any standard medical video source. Digital data in the DICOM format or other popular PC formats such as JPEG, TIFF, etc. can also be acquired.

Images may be acquired in uncompressed or compressed format (lossless or lossy). The lossy compression ratio is selected by viewing the original image and the lossy compressed image side by side and increasing the ratio while retaining clinically significant characteristics. Images that have been lossy compressed have the text "LOSSY xx:1" where xx is the compression ratio placed in the visible, non-diagnostic area of the image.

Related patient information can also be entered or scanned in with a TWAIN compliant scanner. Once acquired, Ultrapro serves as a digital storage for these images. Images are stored on the local hard drive of the computer. Images may be communicated to other Ultrapro workstations or to third-party DICOM 3.0 compliant PACS components. The radiologist may review the images with Ultrapro and create reports. The display of images (contrast, brightness, zoom, etc.) may be adjusted at any time. Annotations may be drawn on images. Distance measurements may be made on images. These image parameters may be saved along with the image while still preserving the original image. This information can be communicated to other workstations through a network or modem. Finally, all of the information may be archived onto optical media for permanent storage.

1.4 Intended Use Statement

Ultrapro is a system that utilizes standard personal computer hardware to acquire, display, communicate and archive diagnostic images. The system is designed for use with FDA approved imaging equipment that provides a video output or a digital output.

1.5 Comparison of Technological Characteristics

	ALI UltraPACS with ALI comPACS	RamSoft Ultrapro
Image Acquisition	Video frame grabber or DICOM input	Video frame grabber, FDA approved film scanner or DICOM input
Compatible Video Signals	NTSC (up to 30 frames/s, 640x480, 256 grayscale, 16.7 million colors) PAL (up to 25 frames/s, 768x576, 256 grayscale, 16.7 million colors)	NTSC (up to 30 frames/s, 640x480, 256 grayscale, 16.7 million colors) PAL (up to 25 frames/s, 768x576, 256 grayscale, 16.7 million colors)
Cine Capability (motion capture)	Yes	Yes
Image Compression	Lossless RLE and Lossy JPEG	Lossless RLE and Lossy JPEG
Lossy Compression Ratio Range	4:1 to 30:1	4:1 to 60:1
Uses JPEG lossy compression in viewing, transmitting and archiving still images	Yes	Yes
Uses Motion JPEG lossy compression for viewing, transmitting and archiving cine images	Yes	Yes
DICOM 3.0 compliant	Yes	Yes
Imaging Modalities	Multi-modality	Multi-modality
Image Display Capability	Yes	Yes
Remote and Local Area Network Communication	Yes	Yes
Image Annotation Capability	Yes	Yes
Archives Image on Optical Media	Yes	Yes

1.6 Conclusion

In conclusion, Ultrapro is substantially equivalent to the ALI product. The determination of substantial equivalence is not based on an assessment of performance tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1998

Naganatha S. Ramanathan, Ph.D.
President
Ramsoft, Inc.
37 Bankview Circle
Toronto, Ontario
Canada M9W 6S6

Re: K982563
"Ultrapro 98, Digital Image
Communications System
Dated: July 22, 1998
Received: July 23, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Dr. Ramanathan:

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): K982563

Device Name: ULTRAPRO 98

Indications For Use:

Ultrapro is a system that utilizes standard personal computer hardware to acquire, display, communicate and archive diagnostic images. The system is designed for use by medical professionals to acquire data from FDA listed imaging equipment such as ultrasound, CT and MRI scanners, x-ray imagers and video cassette recorders that provide a video output or a digital output. Archival is to be performed on media that is FDA listed.

Ultrapro can be configured to use JPEG lossy compression. When lossy compression is used, the compression ratio will be imprinted in the non-diagnostic area of the image. The compression ratio can be adjusted during acquisition.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gerald C. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982563

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)