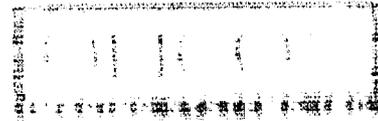


K973959



5 1 0(k) Summary of Safety and Effectiveness

[as required by 21 CFR 807.92©]

DEC 22 1997

Date Prepared: [21 CFR 807.92(a)(1)]

23 September, 1997

Submitter's Information: [21 CFR 807.92(a)(1)]

Olicon Imaging Systems, Inc.
120 Columbia Avenue, Suite 600
Aliso Viejo, CA 92656
phone: (714) 360-1830
fax: (714) 362-1522

Trade Name, Common Name, Classification: [21 CFR 807.92(a)(2)]

Trade Name: Olicon 02 Workstation and/or PACSView software
Common Name: Digital Imaging Workstation
Classification Name: System, Digital Image Communication, accessory

Predicate Device: [21 CFR 807.92(a)(3)]

Applicant: OLICON IMAGING SYSTEMS INC.
510(k) Number: K922164
Device: RAYTEL DIGITAL IMAGING SYSTEMS

Device Description: [21 CFR 807.92(a)(4)]

The Olicon 02-Workstation and/or PACSView™ software is a general purpose computer system consisting of a computer (console, display, keyboard, and mouse) and software which is used to store, communicate, and view radiological images and data in a digital format. Images are stored and displayed utilizing Intel Pentium processing unit with high resolution monitors.

Indications for Use: [21 CFR 807.92(a)(5)]

The Olicon 02-Workstation and/or PACSView™ Software is a device that receives digital images and data from various image sources, (including but not limited to CT Scanners, MR Scanners, Ultrasound systems, R/F Units, Computed & Direct Radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images/data can be stored, communicated, processed, and displayed within the workstation and or across computer networks at distributed locations.



Typical users of this system are trained professionals, including but not limited to physicians, nurses and medical technicians.

Technological Characteristics: [21 CFR 807.92(a)(6)]

The Olicon 02-Workstation and/or PACSView™ software uses the Microsoft Windows NT or 95 operating systems, (as a minimum & depending upon system configuration), and is basically an update of the current Olicon RAYTEL Digital Imaging System Workstation (K922164), and is DICOM 3.0 compliant.

Performance Data: [21 CFR 807.92(b)(1)]

The subject and predicate devices both use standard data communications controls to detect and correct errors.

The subject device complies with UL-1950 Standard for Safety of Information Technology Equipment, Including Electrical Business Equipment.

Conclusion: [21 CFR 807.92(b)(1)]

Similar to the predicate device, the Olicon 02-Workstation and/or PACSView™ software does not contact the patient, nor does it control any life sustaining devices. Images and information being reviewed, processed, relayed, and or transmitted are interpreted by a physician or trained medical personnel, providing ample opportunity for competent human intervention.

The subject device and the predicate share the same certification of conformance to UL-1950 and both function as Digital Imaging Workstations. Device failures which might result in partial or failed transmissions, images, and or data may be recovered by re-transmission after correcting the problems. Passwords are required for operation and to protect against unauthorized use of the system.

Based on the information supplied in this 5109(k), we conclude that the subject devices are safe, effective and substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1997

Olicon Imaging Systems, Inc.
c/o Herman Oosterwijck
Otech, Inc.
6741 Grant Avenue
Plano, TX 75024

Re: K973959
02 - Workstation and PACSView Software
Dated: September 23, 1997
Received: October 16, 1997
Regulatory class: Unclassified
Procode: 90 LMD

Dear Mr. Oosterwijck:

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: K973959

Device Name: Olicon Imaging Systems, Inc. - 02-Workstation and/or PACSView™ Software

Indications For Use:

The Olicon 02-Workstation and/or PACSView™ Software is a device that receives digital images and data from various image sources, (including but not limited to CT Scanners, MR Scanners, Ultrasound systems, R/F Units, Computed & Direct Radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images/data can be stored, communicated, processed, and displayed within the workstation and or across computer networks at distributed locations.

Typical users of this system are trained professionals, including but not limited to physicians, nurses and medical technicians.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over -The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K973959