

DEC 17 1997



5 1 0(k) Summary of Safety and Effectiveness

[as required by 21 CFR 807.92©]

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

20 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 Gateway
 Common Name: Gateway to Digital Imaging Network
 Classification Name: System, Digital Image Communication, accessory

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

Applicant: DEJARNETTE RESEARCH SYSTEMS
 510(k) Number: K963592
 Device: IMAGESHARE PROTOCOL CONVERTING GATEWAY AND/OR SOFTWARE

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

The Olicon Gateway system is a general purpose computer system consisting of a computer (console, display, keyboard, and mouse) and software which runs a protocol conversion software application that uses defined configuration to receive, reformat, and transmit images and demographic information. The system is capable of receiving images from different sources and routes them automatically to predefined destinations.

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

The Olicon Gateway is a uni-directional 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, imaging gateways, or other imaging sources).

The incoming data formats are ACR-NEMA v2.0, DICOM, or SPI (Standard Product Interconnect) or proprietary to the modality source vendor. The Olicon Gateway, converts the imaging or other data into DICOM, ACR-



NEMA v2.0, SPI (Standard Product Interconnect) or proprietary data format and transmits the data to one or more user specified locations across a standard general purpose computing network. 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 Gateway system is a general purpose computer system consisting of a computer (console, display, keyboard, and mouse) and software which runs a protocol conversion software application that uses defined configuration to receive, reformat, and transmit images and demographic information. It functions as a communications protocol converter and not as a permanent image store device. The system is capable of receiving images from different sources and routes them automatically to predefined destinations.

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 Gateway does not contact the patient, nor does it control any life sustaining devices. Images and information being 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 a communications protocol converter to relay and transmit images and data from different modalities and sources to specified locations. Device failures which might result in partial or failed transmissions may be recovered by re-transmission after correcting the problems. Passwords are required for operation and to protect against unauthorized use of the system.

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 17 1997

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

Re: K973793
Protocol Converting Network Gateway
Dated: September 20, 1997
Received: October 6, 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:

Device Name: Olicon Imaging Systems, Inc. - Gateway

Indications For Use:

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

David G. Syron
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices (Optional Format 1-2-96)

Olicon Imaging Systems, Inc. 510(k) Number K973793
Gateway 510(k)