DEC - 2 1997

# 5 1 0(k) Summary of Safety and Effectiveness

## for the Olicon Imaging Systems, Inc. NT Archive Systems

This 5 1 0(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

**Date Prepared:**

4 September, 1997

**Submitter's Information:**

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:**

Trade Name - Olicon Imaging Systems, Inc. ARCHIVE SYSTEMS
Common Name - Digital Archive
Internal Company Names - NT Archive, 02Archive, Archive

**Predicate Device:**

OLICON IMAGING SYSTEMS, INC.
Device: RAYTEL DIGITAL IMAGING SYSTEMS
510(k) Number: K922164
Date Received: 05/08/92
Decision Date: 01/21/93
Decision: Substantially Equivalent
Panel Code device reviewed by:Radiology
Panel Code device classified by:Radiology
Product Code: LMD
Classification: Class II

**510(k) Summary of Safety & Effectiveness** (continued)

**Device Description:**

The NT ARCHIVE SYSTEM is a device for filing digital radiological images for storage and retrieval. The system design is layered with three storage technologies; magnetic, magneto-optical and DLT tape.

**Indications for Use:**

The NT Archive Systems will be used to digitally store medical images for archival together with information about the images. The typical users are trained medial professionals.

**Technological Characteristics:**

The device does not contact the patient, nor does it control any life sustaining devices. Images and information being stored and retrieved are interpreted by a physician, providing ample opportunity for competent human intervention.

The NT ARCHIVE is a Microsoft Windows NT system that is basically an update of the current Olicon Archive (K922164) which is UNIX Solaris based. The NT Archive will provide a 3 tier storage system with built in backup file redundancy.

**Conclusion:**

I certify that the 510(k) Pre-Market Notification for the above referenced device contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to Olicon Imaging Systems, Inc. Archive System - K922164.

1. The NT Archive is subject to and in compliance with the Federal Performance Standards, defined in 21 CFR, part 1000.
2. The NT Archive has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.
3. The submission contains the results of an hazard analysis. All potential hazards have been classified as MINOR.

Richard L. Paulsen
CEO, Olicon Imaging Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 1997

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

Re: K973463
NT Archive Systems
Dated: September 4, 1997
Received: September 12, 1997
Regulatory class: Unclassified
Procode: 90 LMB

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. - NT Archive Systems

**Indications For Use:**

The Olicon Imaging Systems, NT Archive Systems stores and retrieves digital images together with information about the images. The device communicates with other devices via the DICOM standard network protocol.

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)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973463