Merlin

Keen of Eye, Swift of Wing

Merlin Engineering Works 1888 Embarcadero Road, Palo Alto, CA 94303 Tel (415) 856-0900 Fax (415) 858-2302

K971154

2. Summary of Safety and Effectiveness

Submitter:

Merlin Engineering Works, Inc.
1888 Embarcadero Road
Palo Alto, California 94303

JUN 25 1997

Telephone: (415) 856-0900
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Contact: Gerald Engbretson,
Operations Manager / Director, Regulatory Affairs

Device identification:

Trade Name:	MultiPics
Model Number(s):	ME-977
Common Name:	Multiple Picture Digital Scan Converter.
Classification Name:	(A component of) stationary x-ray system, per 21 CFR 892.1680 (or equivalent)

Device(s) to which substantial equivalence is claimed:

K953398	UniScan (a.k.a. Model ME-959)	Merlin Engineering Works, Inc.
K920550	IDP-5100 Interventional Display Processor	Perkins Manufacturing Co.
K904447	SME-3500 Cine Video System	Sony Medical Electronics

Description of the device:

MultiPics (Multiple Picture Scan Converter) is a digital image processing system that can display 2, 3, or 4 pictures on a single video monitor. Additionally, MultiPics has provisions for video scan conversion.

MultiPics provides up to three modes of operation:

DuoPics operation (Model ME-977-2)

In the DuoPics mode, MultiPics accepts two input signals, each at various scan rates, and it outputs high-line video. At the output, each image is one-quarter of its original size with the two images located one beside the other (horizontally spaced), centered vertically, thus fitting into the video frame with no cropping. Each "quarter" picture contains the same information as would be found in a full size, standard rate picture.

TriPics operation (Model ME-977-3)

In the TriPics mode, MultiPics accepts three input signals, each at various scan rates, and it outputs high-line video. At the output, each image is one-quarter of its original size with two of them located one beside the other (horizontally spaced) in the bottom half of the picture, and the other located above the two, thus fitting into the video frame with no cropping. Each "quarter" picture contains the same information as would be found in a full size, standard rate picture.

QuadPics operation (Model ME-977-4)

In the QuadPics mode, MultiPics accepts four input signals, each at various scan rates, and it outputs high-line video. At the output, each image is one-quarter of its original size with two of them located one beside the other (horizontally spaced) in the bottom half of the picture, and the other two located one beside the other (horizontally spaced) in the top half of the picture, thus fitting into the video frame with no cropping. Each "quarter" picture contains the same information as would be found in a full size, standard rate picture.

When used in conjunction with a Video Scan Converter capable of converting from high-line to low-line, such as Merlin's UniScan (submission K953398), the resulting MultiPics image can be recorded on standard VHS, S-VHS, and other readily available recorder formats, and can be viewed with standard video monitors.

Intended use of the device:	The intended use for MultiPics is conversion and combining of X-ray (stationary, C-arm, angiography, etc.), nuclear medicine, magnetic resonance, and ultrasound images either directly from their source, or from an intermediate storage device (like a video tape or video disk), for use on display monitors, optical, tape, disk, or other apparatus requiring a video signal. MultiPics is not intended to have any patient contact. The use of MultiPics is indicated whenever multiple images (2, 3, or 4) are required to be shown together in a single image/display, and a high-line rate (e.g., 1049 lines @ 30 frames/sec or 1249 lines @ 25 fps) video signal is required.
Summary of how the technological characteristics compare to predicate device(s):	MultiPics and the predicate devices are real-time video processing systems designed to convert monochrome video images from one format to another (e.g., low line-rate to high line-rate, or visa versa) and/or to convert from full size images to quarter size images. MultiPics and at least two of the predicate devices (Merlin UniScan) utilize similar technology to perform the scan conversion. These systems both convert the incoming analog video signal to digital form using 8-bit analog-to-digital converters, process the signals in the digital domain, and convert back to analog video using 8-bit digital-to-analog converters for the output. MultiPics and (applicable portions of) the other predicate devices (Perkins IDP-5100 and Sony SME-3500) both reduce one or more full size images to smaller images, and combine them in one full size picture using digital processing.
Summary of (non-clinical) performance tests and how their results support a determination of substantial equivalence:	MultiPics was tested to ensure that it meets the appropriate requirements of RS-170 and RS-343A. The data demonstrates that MultiPics meets these standards, as appropriate to the specific signal, as is the case for the predicate devices. In addition, MultiPics was tested in accordance with SMPTE RP-133. The system correctly compensates for aspect ratio changes in accordance with the requirements of the particular scan conversion selected. In addition, the system permits low-contrast imaging resolution at the 1% level.
Conclusions drawn from the performance tests:	MultiPics is electrically compatible with industry standard monochrome video signals. The image quality is preserved (within the limits of standard video technology and the line rates selected).

QuadPics operation (Model ME-977-4)

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When used in conjunction with a Video Scan Converter capable of converting from high-line to low-line, such as Merlin's UniScan (submission K953398), the resulting MultiPics image can be recorded on standard VHS, S-VHS, and other readily available recorder formats, and can be viewed with standard video monitors.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gerald C. Engbretson
Operations Manager
and Director of Regulatory Affairs
Merlin Engineering Works
1888 Embarcadero Road
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JUN 25 1997

Re: K971154
Merlin MultiPics
Dated: March 27, 1997
Received: March 28, 1997
Regulatory class: II
21 CFR 892.1680/Procode: 90 LMD

Dear Mr. Engbretson:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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 (if known): _____

Device Name: **MultiPics**

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David W. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971154

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

(Optional Format 1-2-96)