Keen of Eye, Swift of Wing

MAY 22 1998 K974882

Merlin

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

2. Summary of Safety and Effectiveness

Submitter:

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

Telephone: (650) 856-0900
Facsimile: (650) 858-2302

Contact: Gerald Engbretson,
Operations Manager and Director of Regulatory Affairs

Device identification:

Trade Name: DownScan LT

Model Number: ME-509

Common Name: Video Scan Converter (or Digital Scan Converter)

Classification Name: Image Processing System

Device(s) to which substantial equivalence is claimed:

K953398	UniScan	Merlin Engineering Works
K970451	DownScan 120	Merlin Engineering Works

Description of the device:

DownScan LT is a digital image processing system that can convert from high line rate video standard of 1023-1125/60 or 1249/50 to low line rate video standards of 525/30 or 625/25. Housed in a 1 3/4" EIA half-rack mount chassis, DownScan LT operates from 100V to 240V AC power.

Intended use of the device:

The intended use for DownScan LT is conversion 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 or disk recorders, or other apparatus requiring a standard frame rate video signal (30 or 25 frames/second).

The use of DownScan LT is indicated whenever the source and destination of a video signal are incompatible due to different line rates or other signal attributes, and a standard frame rate video signal is required.

DownScan LT is intended for use in patient care areas, but is not intended to have any patient contact.

Summary of how the technological characteristics compare to predicate device(s):	DownScan LT and the predicate devices are real-time video processing systems which are designed to convert monochrome video images from one video format to another. The main difference between DownScan LT and one of the predicates (Merlin UniScan) is that DownScan LT converts video from high line rate to low line rate formats, where the predicate converts from low line to high line (upscan mode) as well as high line to low line (downscan mode). The only differences between DownScan LT and the other predicate (Merlin DownScan 120) are a varying clock frequencies and the ability of the predicate to input video at twice the standard frame rate (with the DownScan 120). DownScan LT and the predicate devices utilize similar technology to perform their functions. These systems all 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.
Summary of (non-clinical) performance tests and how their results support a determination of substantial equivalence:	DownScan LT was tested to ensure that it meets the appropriate requirements of RS-170 and RS-343A. The data demonstrates that the DownScan LT meets these requirements, as is the case for the predicate devices. In addition, DownScan LT was tested in accordance with SMPTE RP-133. The system correctly compensates for aspect ratio changes, and it permits low-contrast imaging resolution at the 1% level.
Conclusions drawn from the performance tests:	DownScan LT is electrically compatible with industry standard monochrome video signals. The image quality is preserved (within the limits of standard video technology).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1998

Gerald C. Engbretson
Operations Manager and
Director of Reguulatory Affairs
Merlin Engineering Works
1888 Embarcadero Road

Re: K974882
Merlin DownScan LT
Dated: March 24, 1998
Received: March 25, 1998
Unclassified/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 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): _____

Device Name: **DownScan LT**

Indications For Use:

The use of DownScan LT is indicated whenever the source and destination of a video signal are incompatible due to different line rates or other signal attributes, and a standard frame rate video signal (30 or 25 frames/second) is required. Examples include conversion 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, or disk recorders, or other apparatus requiring a standard frame rate signal.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974882

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

(Optional Format 1-2-96)