



K971153

2. Summary of Safety and Effectiveness

Submitter: Merlin Engineering Works, Inc.
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Palo Alto, California 94303

JUN 25 1997

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Contact: Gerald Engbretson,
Operations Manager / Director, Regulatory Affairs

Device identification: Trade Name: SplitScreen
Model Number(s): ME-975
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.

Description of the device:

SplitScreen is a digital image processing systems that can display 2 pictures side-by-side on a single video monitor. Additionally, SplitScreen has provisions for video scan rate conversion.

SplitScreen accepts two input signals at various scan rates, and it outputs video at high-line rate. Both images share the full video frame by splitting them with a vertical boundary. The position of the boundary can be adjusted right or left (thus adjusting the relative amounts of each image viewed), and each image can be panned horizontally within each split area. The result is two images, each of which is full height but cropped horizontally. The output composite image is compatible with high-resolution monitors capable of displaying high-line rate video which is compatible with EIA standard RS-343A.

When used in conjunction with a Video Scan Converter capable of converting from high-line to low-line rate, such as Merlin's UniScan (submission K953398), the resulting SplitScreen 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 SplitScreen 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.

The use of SplitScreen is indicated whenever two images are required to be shown together side-by-side 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. SplitScreen is not intended to have any patient contact.

Summary of how the technological characteristics compare to predicate device(s):

SplitScreen 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/full view images to other size/other view images. SplitScreen and all of the predicate devices utilize similar technology to perform the scan conversion. 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.

SplitScreen and one of the other predicates (Perkins IDP-5100) produce outputs where parts of one input image cover parts of the other input, since full sized/full view images must either be sized or cropped to allow multiple images on a single display. The Perkins unit does this by shrinking one of the images to quarter size (covering up an equivalent amount of the second image), while SplitScreen does this by horizontally cropping both images, keeping both of them full height.

Summary of (non-clinical) performance tests and how their results support a determination of substantial equivalence:

SplitScreen was tested to ensure that it meets the appropriate requirements of RS-170 and RS-343A. The data demonstrates that SplitScreen meets these standards, as appropriate to the specific signal, as is the case for the predicate devices.

In addition, SplitScreen 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:

SplitScreen 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).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gerald Engbretson
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Regulatory Affairs
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Re: K971153
Splitscreen ME-975 Multiple Picture
Digital Scan Converter
Dated: March 27, 1997
Received: March 28, 1997
Regulatory Class: II
21 CFR 892.1680/Procode: 90 LMD

JUN 25 1997

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): _____

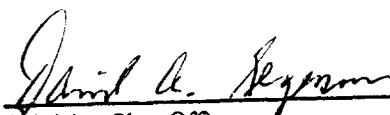
Device Name: **SplitScreen**

Indications For Use:

The use of SplitScreen is indicated whenever two images are required to be shown together side-by-side 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. Examples include conversion / combining of X-ray (stationary, C-arm, angiography, etc.), nuclear medicine, magnetic resonance, and/or 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 high-line rate video 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 K971153

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____