Merlin

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K970457

2. Summary of Safety and Effectiveness

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Submitter:	Merlin Engineering Works, Inc. 1888 Embarcadero Road Palo Alto, California 94303 Telephone: (415) 856-0900 Facsimile: (415) 858-2302 Contact: Gerald Engbretson, Operations Manager / Director, Regulatory Affairs	
Device identification:	Trade Name:	DownScan 120
	Model Number:	ME-954
	Common Name:	Video Scan Converter (or Digital Scan Converter)
	Classification Name:	(A component of) stationary x-ray system, per 21 CFR 892.1689 (or equivalent)
Device(s) to which substantial equivalence is claimed:	K953398 UniScan	Merlin Engineering Works
Description of the device:	DownScan 120 is a digital image processing system that can convert from very-high-line rate video standard of 1023-1049/60 or 1249/50 (~64 KHz horizontal frequency, often referred to as "flicker free" or "fast" video) to high-line rate video standards of 1023-1049/30 or 1249/25, or to low-line rate video standards of 525/30 or 625/25. Housed in a 1 3/4" EIA rack mount chassis, DownScan 120 operates from 100V to 240V AC power.	
Intended use of the device:	The intended use for DownScan 120 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 120 is indicated whenever the source and destination of a video signal are incompatible due to different line and/or frame rates, and a standard frame rate video signal is required. DownScan 120 is intended for use in patient care areas, but is not intended to have any patient contact.	

Technological characteristics of the device:	DownScan 120 consists of an enclosed sheet metal chassis housing one main printed wiring assembly, one secondary printed wiring assembly, and the power supply (100-240 VAC input and ±15 VDC, ±5 VDC outputs). DownScan 120 uses standard SSI/MSI/LSI semiconductor technology. DownScan 120 utilizes eight basic electronic circuits on the primary printed wiring assembly. They are: input analog video conditioning circuit, analog-to-digital conversion circuit, memory circuits, various control circuits, digital-to-analog conversion circuit, two clock circuits, and output analog video conditioning circuit. All of the processing is done in the digital domain. The analog-to-digital converter changes the analog video to an 8-bit digital bus. That digital bus is sent to the memories for processing. Memory control circuits manage the locations and the timing of how the video is being stored in the memories and then read from memory before sending the resultant signal to the 8-bit digital-to-analog circuit. The write clock generator provides clock timing for analog-to-digital conversion, the memories and the memory control circuits. The read clock generator provides read clock timing for the memories and the digital-to-analog circuits.
Summary of how the technological characteristics compare to predicate device(s):	DownScan 120 and the predicate device are real-time video processing systems which are designed to convert monochrome video images from one video format to another. The only differences are a higher clock frequency and the ability to input video at twice the standard frame rate. DownScan 120 and the predicate device utilize similar technology to perform their functions. 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.
Summary of (non-clinical) performance tests and how their results support a determination of substantial equivalence:	DownScan 120 was tested to ensure that it meets the appropriate requirements of RS-170 and RS-343A. The data demonstrates that the DownScan 120 meets these requirements, as is the case for the predicate device. In addition, DownScan 120 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 120 is electrically compatible with industry standard monochrome video signals. The image quality is preserved (within the limits of standard video technology).