

DEC 9 1996

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Section 2
510(k) Summary & Certification

The following is a Summary & Certification of the SimulScope® Bedside Auscultation System

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the safety and/or effectiveness for an SimulScope® Bedside Auscultation System.

Printed Name J. Harvey Knauss

Signature

J. Harvey Knauss

Title

Owner

Date

May 16, 1996

Delphi Consulting Group, P. O. Box 932, Stafford, Texas 77477, 713-723-8169
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CLASSIFICATION NAME:	STETHOSCOPE, ELECTRONIC
COMMON/USUAL NAME:	STETHOSCOPE, ELECTRONIC
PROPRIETARY NAME:	SimulScope® Bedside Auscultation System
CLASSIFICATION:	21 CFR Part 882.1835, Amplifier, Physiological Signal, Class II
PERFORMANCE STANDARDS:	None established
INDICATIONS	The SimulScope® Bedside Auscultation System allows the user to amplify heart, lung and bowel sounds and transmit them via infrared energy to wireless headphone worn by more than one listener. The system uses an electronic stethoscope connected to a transmitter unit and a receiving unit(s) for each listener.
CONTRAINDICATIONS	None known. Accepted clinical practices must always be observed.

SUBSTANTIAL EQUIVALENCE

The SimulScope® Bedside Auscultation System material and design is substantial equivalent to the Graphic Auscultation System from Blood Line Technology, Incline Village, Nevada 89450-3937 and the DSP-200 Digital Stethoscope from International Acoustics Incorporated, Palatine, Illinois 60067.

SUBSTANTIAL EQUIVALENCE

Comparison of features and principles of operation between the SimulScope® Bedside Auscultation System and other devices in the market via Section 510(k) of the Act.

Parameter	SimulScope®	Graphic Auscultation	DSP-200
Acoustic Operation	No	Yes	No
Electronic Operation	Yes	Yes	Yes
Battery Operation	Yes	Yes	Yes
AC Powered Operation	Yes	No	Yes
Frequency Range	30 Hz to 4 KHz	50 Hz - 2 KHz	50 Hz - 4 KHz
Equalizer	Yes (8 band)	Switchable filters	No
Infrared Sound Transmission	Yes	No	No
Unit Weight	4 Lbs	10.8 Oz	Unknown
Electronics in chest piece	No	Yes	No
Speaker in tubing	Yes	Yes	No
Accessory jack output	Yes	Yes	Yes
Output for a number of listeners	Yes	Yes	Yes
Micro Processor	No	Unknown	Yes