

## Summary of Safety and Effectiveness

K946349

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92 and was prepared April 27, 1995.

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Common Name: Bidirectional Vascular Doppler with Spectral Analysis.

Proprietary Name: Stenodoc

Classification Name: Nonfetal ultrasonic monitor, 21 CFR 892.1540.

Classification: Classification of this ultrasonic device under Section 513 of the act is Class II.

Predicate Device: The Stenodoc Bidirectional Vascular Doppler with Spectral Analysis is substantially equivalent to the Multigon 500A Vascular Spectrum Analyzer with Doppler, Reference K850435, which was declared substantially equivalent to predicate devices May 5, 1986.

Description: Stenodoc is a mains independent portable continuous wave Doppler ultrasound device with two pen-shaped split-D transducers operating at 4 MHz and 8 MHz. A 512 point fast Fourier transform (FFT) is performed on the returned signal. The spectral distribution of blood flow is represented as a frequency over time diagram with intensities represented by different shades of gray. The diagram is displayed on a liquid crystal display (LCD). Measurements can be annotated with the patient's name, vessel name and a diagnosis and can be stored on a built-in hard-disk for later evaluation.  
Size: 3" x 13.5" x 10" (Height/Width/Depth) Weight: 9 lbs.

Intended use: Detection and analysis of vascular disease in peripheral vessels. Evaluation of degree and site of a stenosis. Detection of occlusions and flow disturbances. Determination of vessel type and location. Measurement of relative flow velocity. Not intended for fetal use.

## Summary of technological characteristics of Stenodoc and the predicate device.

Characteristic	STENODOC™	Multigon 500A
Device Type	Bidirectional Doppler	Bidirectional Doppler
Ultrasound mode	continuous wave	continuous wave
Transducers	4 and 8MHz split D	4 and 8MHz split D
I <sub>SPTA</sub> 8 MHz Probe	< 94 mW/cm <sup>2</sup>	90 mW/cm <sup>2</sup>
I <sub>SPTA</sub> 4 MHz Probe	< 80 mW/cm <sup>2</sup>	69 mW/cm <sup>2</sup>
Maximum Doppler frequency detection	32 kHz	35 kHz
AD-Converter	12 bit	8 bit
Spectral Analysis	512 pt. FFT/direction	256 pt. FFT overall
FFT calculation every	10 ms	6.5 ms
Physical Device Type	Laptop-Computer style	Desktop-Computer Style
Display	9.5" diagonal LCD	9" diagonal tube
Calculations	Maximum, Mode and Mean frequency, spectral broadening, pulsatility and resistance index	Maximum, Mode and Mean frequency, Spectral broadening