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## 14. 510(k) Summary

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 Ultramax Canada Inc.  
 5571 Sandiford Place  
 V7E 5M5 Richmond, B.C.  
 Canada

tel 604-241-1019  
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Date 18th December 1995

The device:

Trade name Ultramax, an ultrasonic system to assist in the diagnosis of maxillary and frontal sinusitis

Common name Ultramax Sinus Scanner

Classification name/class Nasal Sinus scanning/measurement device  
77LWI

The device to which the equivalence is claimed:

Trade name Echoline 1000 ultrasound system for scanning sinus cavities

Common name Echoline Sinus Scanner

Classification name/class Nasal Sinus Scanning/measurement device  
77LWI

Manufacturer American Electromedics Corp.  
Sagamore Park Road, Hudson, NH 03051  
phone 603-880-6300

510(k) number Not found

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Comparison of the technological characteristics: a summary.

	Ultramax	Echosine
Description of the method and target organs	Ultrasound system to scan nasal sinuses	Ultrasound system to scan nasal sinuses
Target population	Patients with suspected sinusitis	Patients with suspected sinusitis
Method to detect sinusitis	shows liquids in the sinuses	shows liquids in the sinuses
Ultrasound mode	pulse-echo	pulse-echo
Measuring Range	0-40 or 0-80mm	0-30 or 0-80mm
Leds/Markers on the display	2.5 mm or 5 mm	2 mm steps
Image freeze	yes	yes
Controls	receiver gain depth range	receiver gain depth range CRT focus
Probe design <u>contact material</u>	round flat <u>epoxy</u>	round <u>epoxy</u>
Beam	unfocused	focused
Probe frequency	3 MHz	3.5 MHz
Probe diameter	8 mm	13 mm
Probe area	50 mm <sup>2</sup>	133 mm <sup>2</sup>
Pulse duration	0.9 us	0.3- 0.5 us
Maximum Ultrasonic Power		0.9 mW
MI (mean)	0.0962	
Pulse repetition fr.	300 Hz fixed	.... cont.

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continued:

	Ultramax	Echosine
Display	a bar of light emitting diodes (LEDs)	cathode ray tube (CRT)
Echo display mode		
-low intensity	brightness of one LED	amplitude of a peak on CRT
-high intensity	breadth of the echo complex	breadth of the echo complex
Hard copy	Polaroid camera (optional)	printer (optional)
Power supply	9 V rechargeable battery + 120V charging unit	120V 50-60Hz mains

**Conclusions:**

The Ultramax and the Echosine diagnostic ultrasound systems are substantially equivalent.

**Description of the device**

**Indications for use:** Ultramax ultrasonic diagnostic system is intended to assist the physician in the diagnosis of maxillary and frontal sinusitis by detecting fluid in the sinus cavity.

**Principles of operation:** The Ultramax is an A-scan, pulse-echo device, equipped with a single unfocused flat 8 mm 3 MHz transducer. Pulse repetition rate is fixed at 300 Hz. The only controls on the device are the receiver gain, and the range that can be selected between "8" (0-8 cm), "4" (0-4 cm) and "4E" (4-8 cm). These selections do not effect the emitted acoustic power.

**Power source:** Rechargeable 9 V battery. Charging unit with 110 V hospital grade charger.

**Composition:** Probe, probe cable (optional), extension tube, hand held unit, charging unit, gel bottle (empty), calibration check rod.

**Measures:** Length 22 centimeters, weight 170 grams.

**Performance parameters:** Maximum values are for MI: 0.1195,  $I_{SPTA.3}$  0.230 mW/cm<sup>2</sup> and  $I_{SPPA.3}$  0.956 W/cm<sup>2</sup>. The results are all less than those for diagnostic use, given by the FDA.