

K960374

## APPENDIX C

### SUMMARY OF SAFETY AND EFFECTIVENESS

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The Ultralase Ultracut 2000 is equivalent to the predicate device Cavitron Corporation's Cavitron Ultrasonic Surgical Aspirator (CUSA). The Ultracut 2000 has the same general intended use, similar principles of operation, and similar technological characteristics as the predicate device. The Ultracut 2000 and CUSA are both ultrasonic surgical instruments intended for use to cut or fragment tissue, bone, or organs in orthopedic surgery.

### Comparison Chart

	Ultracut 2000	CUSA (Model 200H)
<i>510(k)</i>	Applied For	K801623
<i>Console Dimensions (in)</i>	4.5 x 12.25 x 11.125	76 x 23 x 26
<i>Power Specifications</i>	115VAC; 50/60 Hz	115VAC; 50/60 Hz
<i>Footswitch Control</i>	Yes	Yes
<i>Intended Use</i>	Ultrasonic Surgery	Ultrasonic Surgery
<i>Frequency</i>	40kHz	37kHz
<i>Vibration Amplitude</i>	Variable, 0-500 $\mu$	Variable, 0-355 $\mu$
<i>Power</i>	Variable, 0-100 watts	Variable, 0-70 watts
<i>Timer</i>	Yes (1 sec - 100 min)	Yes (0 - 99 min)
<i>Aspiration</i>	Yes	Yes
<i>Irrigation</i>	Yes	Yes
<i>Modes of Operation</i>	Continuous Pulsed On/Off	Continuous Pulsed On/Off
<i>Handpiece Frequency</i>	40kHz	37kHz
<i>Dimensions (inches)</i>	L 5.75 x D 1.25	L 6.75
<i>Removable Surgical Tips</i>	Yes	Yes
<i>Tip Material</i>	Titanium or Stainless Steel	Titanium
<i>Transducer</i>	Piezoelectric	Magnetostrictive
<i>Sterilization</i>	Autoclave	EtO or Steam