

MAY 21 1999

Sonokinetics
SONOTOME™ System

510K Submission

K990572

**510K Summary
Sonokinetics**

1. **Sponsor Name**
Sonokinetics
14 Equestrian Drive
North Reading, MA 01864
Contact Individual: Debbie Iampietro
QRC Consulting Associates
7 Tiffany Trail
Hopkinton, MA 01748
(508)-435-9893
2. **Device Name**
Proprietary Name: SONOTOME™ System
Common/Usual Name: Ultrasonic Aspiration Device
Classification Name: LFL
3. **Identification of Predicate or Legally Marketed Device**
The Sonokinetics SONOTOME™ System is a mechanical ultrasonic surgical aspirator which is substantially equivalent to the following predicate devices: SonoKinetics' ACRYL-X™ II System (K930629) and ValleyLabs Inc. CUSA® 200 System (K853143, K864983, K884412, K884413, K894600, K910696).
4. **Device Description**
The SONOTOME™ System contains three subsystems: ultrasonic energy, irrigation and aspiration. The SONOTOME™ System uses a hollow titanium tip PROBE mounted to a reusable handpiece. The ultrasonic power generator provides energy to the handle which converts it into ultrasonic energy at the tip. The irrigation and the ultrasonic energy are activated by depressing the foot pedal. The vibrating probe mounted on the hand piece is then applied to the tissue desired to be removed. The application of ultrasonic energy through the tip breaks down the tissue through a cavitation action. The resultant debris is aspirated through the probe tip and into a disposable trap between the handpiece and the vacuum canister. The flow of saline is maintained to reduce the temperature of the probe and to provide for a means of irrigation to the surgical site.
5. **Intended Use**
The SONOTOME System is intended for the following indications:
Breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN, Thoracic.

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6. Comparison of Technological Characteristics

	<i>CUSA® NS-200 Valleylab Inc.</i>	<i>ACRYL-X™ II SYSTEM SonoKinetics</i>	<i>SONOTOME™ Sonokinetics</i>
K#	K910696, 894600, K884413, K884412	K930629	
Intended Use	Breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN, Thoracic	Removal of thermoplastic cement from bones in revision procedures	Breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN, Thoracic
Basic operating principle	Metal tip driven by ultrasound causing tissue fragmentation and aspiration through tip	Metal tip driven by ultrasound, cooling and aspiration of plastic through tip	Metal tip driven by ultrasound causing tissue fragmentation and aspiration through tip
System console	Self-contained with ultrasonic, irrigation, and aspiration subsystems	Self-contained with ultrasonic, irrigation, and aspiration subsystems	Self-contained with ultrasonic, irrigation and aspiration subsystems
Amplitude of vibration of tip	Adjustable up to 355 microns	240 microns, peak to peak	240 microns, peak to peak
Vibration frequency	23 kHz	20 kHz	20 kHz
Irrigation flow rates	1.5-50cc/min	10-400 ml/min	10-400ml/min
Aspiration	0-24 in. Hg	5-15 in. Hg.	5-15 in. Hg.
Disposable components		Surgical Tips, suction trap, irrigation/suction tubing set	Surgical Tips, suction trap, irrigation/suction tubing set
Power requirements	100-120 VAC, 15amps, 50-60 Hz 200-240 VAC, 10amps, 50-60 Hz	105-130 v a-c, 60 Hz, 500 watts	105-130 v a-c, 60 Hz, 500 watts

7 Performance Testing

Since this 510K is for expanded indications only, and the device has not been modified from that cleared under K930629, no further performance testing was performed.



MAY 21 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sonokinetics, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting Associates
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K990572
Trade Name: SONOTOME™ System
Regulatory Class: Unclassified
Product Code: LFL
Dated: February 22, 1999
Received: February 23, 1999

Dear Ms. Iampietro :

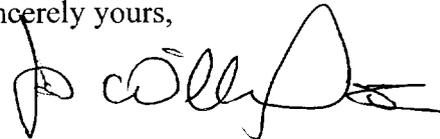
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990572

Device Name: SONOTOME™ System

Indications For Use: The SONOTOME System is intended for the following indications:

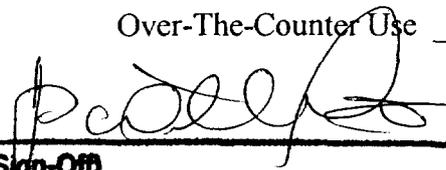
Breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN, Thoracic Surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR Over-The-Counter Use



(Division Sign-Off)

Division of General Restorative Devices
510(k) Number K990572

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