

## **510(K) Summary of Safety and Effectiveness for CITEI's Allegro Ultrasonic Soft Tissue Aspirator**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

**Submitter:** California Institute of Tissue Engineering and Instrumentation  
205 South West Street, Suite A  
Visalia, CA 93291

**Contact Person:** Jeff Wheaton (209) 625-9730  
(209) 695-3124 Fax

**Date Prepared:** Friday 30 January 1998

**Proprietary Name:** Allegro Ultrasonic Soft Tissue Aspirator

**Classification Name:** Ultrasonic Surgical Instrument

**Device Classification:** Class II

**Device Product Code:** 79LFL

**Intended Use:** Facilitates fragmentation and emulsification of soft tissues in General and Plastic & Reconstructive Surgery.

**Device Description:** The Allegro is comprised of a power conditioner (110/120 volts AC), a microcomputer, a control panel, a signal generator, a BNC output, and a separate surgical handpiece. The power conditioner serves to buffer the system from commercial electrical discontinuities and provides a continuous electrical signal to Allegro's components. The microcomputer integrates Allegro's system components and provides a user-friendly control interface. The control panel provides for user input and system settings and displays. The signal generator creates electrical current in programmable waveforms (20-25 kHz). The BNC output connects the system to the surgical handpiece. The surgical handpiece contains the electromotive engine (piezoelectric ceramic stack), the infiltration/aspiration port, and the ultrasonic surgical probe. The electrical waveforms sent to the handpiece excite the motor stack and cause high-frequency, small amplitude motion of the ultrasonic surgical probe. Motion at the tip of the probe fragments local soft tissue, which is then aspirated through the probe.

**Sterility Information:** This product is not supplied sterile.

**Predicate Devices:** The Allegro Ultrasonic Soft Tissue Aspirator is similar in technical design and operation to other surgical devices with irrigation, suction, and ultrasound which the FDA has determined to be substantially equivalent to pre-amendment devices as depicted below:

Mentor Ultrasound Assisted Tissue Removal System (K970471)

Valleylab CUSA® System (K910696)

SMEI Sculpture (K971609)

Ultra-Safe (K962525)

**Non-Clinical Data:** Electrical signals generated by CITEI's device (sinusoidal amplitude, 37-45 kHz) are comparable to the indicated predicate devices.

Motion at the probe tip ( $\geq 0$  or  $\leq 500$   $\mu\text{m}$ ) is comparable to the indicated predicate devices.

The motion or amplitude of the working end of the device is primarily in a vertical motion at the rate of 20-25 kHz.

Power consumption (0-100 watts) is similar to the indicated predicate devices.

Ultrasonic probe design and construction (titanium and/or stainless steel) is similar to the indicated predicate devices.

**Conclusion:** The stated similarities between CITEI's Allegro Ultrasonic Soft Tissue Aspirator and the indicated predicate devices motivate the determination that these devices are substantially equivalent.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jeff Wheaton  
Project Manager  
California Institute of Tissue Engineering and Instrumentation  
205 South West Street, Suite A  
Visalia, California 93291

Re: K980895  
Trade Name: Allegro Ultrasonic Soft Tissue Aspirator  
Regulatory Class: II  
Product Code: LFL  
Dated: August 05, 1998  
Received: August 11, 1998

Dear Mr. Wheaton:

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.

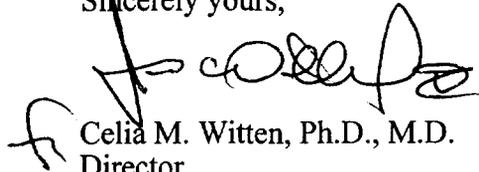
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Jeff Wheaton

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

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): K980895

Device Name: ALLEGRO SOFT TISSUE ASPIRATOR

Indications For Use:

The Allegro is indicated for use in the following surgical specialties when the fragmentation, emulsification and aspiration of soft tissue is desired.

- General Surgery
- Plastic and reconstructive Surgery

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K980895

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_