



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Soloff
President
Sonics & Materials Inc.
Kenosia Avenue
Danbury, Connecticut 06810

JUL 25 1997

Re: K971533
Trade Name: *VIBRA-SURGE*TM System Model VS2120 Ultrasonic Surgical
Instrument
Regulatory Class: Unclassified
Product Code: LFL
Dated: April 23, 1997
Received: April 28, 1997

Dear Mr. Soloff:

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.

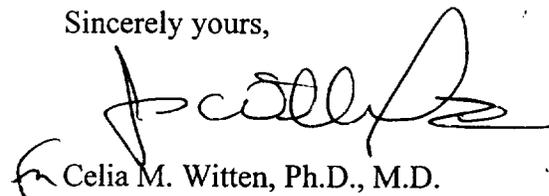
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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

JUL 25 1997

K971533

510(k) Summary - Sonics and Materials, Inc.
VIBRA~SURGE™ System Model VS2120

This summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR 807.92

Submitter: Sonics & Materials, Inc.
Kenosia Avenue
Danbury, CT 06810
(203)744-4400

Contact Person: Alan Broadwin (914) 833-2649

Date Prepared: 4/23/97

Trade or Proprietary Name: VIBRA~SURGE™ System VS2120

Common, Usual or Classification Name: Instrument, Ultrasonic Surgical

Predicate Devices: MedSonic Incorporated Alliger Ultrasonic Surgical System Model AUSS-1; Valleylab CUSA® 200 Series Ultrasonic Surgical Aspirator; Sharpian ULTRA Ultrasonic Surgical Aspirator.

Device Description: The VIBRA~SURGE™ System VS2120 is comprised of a generator, operating at one of several possible standard line voltages, contained in a console which feeds a 20-22 kHz electrical signal to a surgical handpiece containing piezoceramic crystals. These crystals convert the electrical energy into mechanical motion. This mechanical motion has the same frequency of 20-22 kHz. Fragmentation of unwanted tissues occurs at the end of the tip which is hollow allowing the use of a vacuum source to remove these fragments.

Intended Use: Aids in the fragmentation, emulsification and removal of soft tissue in General and Plastic & Reconstructive Surgery

Technological Characteristics: The VIBRA~SURGE™ System VS2120 is similar in design, material and operating parameters to the predicate devices indicated above. Consequently no new safety or efficacy issues exist and this device was determined to be substantially equivalent.

