K992026

SEP 2 3 1999

# 510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

**Date Prepared:**

17 July 1999

**Submitter's Information:**

Soring GmbH Medizintechnik
Justus-v.Liebig 10
25451 Quickborn
Germany

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**Trade Name, Common Name, Classification:**

| | |
|---|---|
| Trade Name: | Sonoca 300 |
| Common Name: | Instrument, Ultrasonic Surgical |
| Classification Name: | General & Plastic Surgery |

**Predicate Device:**

| | |
|---|---|
| Applicant: | Söring GmbH |
| 510(k) Number: | K942095 |
| Device: | Sonoca III |

**Device Description:**

SONOCA 300 is an upgraded version of the SONOCA III having K9942095.

During the use of an ultrasonic dissector, power is transmitted from a longitudinal vibrating probe tip in the contact zone to tissue. The probe with the integrated aspiration/irrigation function collects the cell and tissue fragments.

The SONOCA 300 is not an alternative to conventional surgery but a supplementary tool for the selective dissection of human tissue.

Where as the scalpel and other methods of cutting are basically limited to cutting tissue. The SONOCA 300 can be used to cut, irrigate, and suction at the surgical site.

**Indications for Use:**

The SONOCA 300 is an instrument intended for selected ultrasound dissection, fragmenting, emulsifying, and aspiration of human tissue and adjunctive irrigation and suction at the operation site during multi-medical discipline surgery including: General Surgery, NE, PED, Thoracic, UR, and GI modalities but not including CV, Ent, Ortho or suction Lipectomy.

# 510(k) Summary of Safety & Effectiveness

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The intended use of the modified device, as described in its labeling, has not changed as a result of the modifications to the predicate device.

**Performance Data:**

The subject and predicate devices both use standard data communications controls to detect errors. The subject device complies with IEC 950 – Safety of Information Technology Equipment, CISPR 22, class A – Electromagnetic Compatibility, IEC-801-2, IEC-801-3 – Electromagnetic Compatibility, IEEE 1003.1 – General Electrical Safety for medical devices, IEC 601-1 –Electrical Safety for medical devices using RF-power, IEC 601-2-2 – Ultrasonic surgical devices, DIN EN 61847

**Conclusion:**

Similar to the predicate device, the Sonoca 300 does not control any life sustaining functions or services. The device and the predicate device share the same conformance to performance standards and both function as Ultrasonic Dissectors. Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1999

Soring GmbH Medizintechnik
c/o Mr. Carl Alletto
3200 Dogwood Court
Cincinnati, Ohio 45140

Re: K992026
Trade Name: Sonoca 300
Regulatory Class: II
Product Code: LFL and BTA
Dated: August 16, 1999
Received: August 16, 1999

Dear Mr. Alletto:

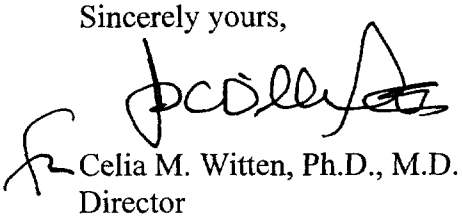
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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: K992026

Device Name: Soering, SONOCA 300

Indications for Use:

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over -The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992026