OCT 2 2 1999

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

K993265

Date Prepared:

28 July 1999

Submitter's Information:

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

Telephone: 49 4106-6100-0
Fax: 49 4106-6100-10
Email: info@soering.com

Trade Name, Common Name, Classification:

Trade name:	Söring GmbH, ARCO 3000, ARCO 2000, ARCO 1000, MBC 601, MBC 600
Common name:	Electrosurgical conductive gas coagulation
Classification name:	General Surgery

Predicate Device:

Applicant:	Söring GmbH
510(k) Number:	K954171
Device:	ARCO MBC, ARCO MC, MBC 500

Device Description:

ARCO 3000, ARCO 2000, ARCO 1000, MBC 601, MBC 600 are an upgraded version of the ARCO MBC, ARCO MC, MBC 500 as described in K954171.

During the use of RF surgery devices, power is transmitted via an electrode in the contact zone to tissue. The active electrode then cuts or coagulates (depending upon its design and adjusted power form) the tissue. The inert gas coagulation uses an ionized beam of an inert gas (argon) to transmit the electrical energy to the tissue to achieve a coagulation effect.

Indications for Use:

The devices are intended to cut and or coagulate (soft) biological tissue with gas enhanced coagulation in ARCO models, e.g. during general surgical procedures.
Typical users of this system are trained medical professionals.

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 – Special specifications for the safety of RF-surgery units

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Conclusion:

The intended use of the modified devices, as described in its labeling, has not changed as a result of the modifications.
Similar to the predicate device, the ARCO 3000 Family do not control any life sustaining functions or services. The devices and the predicate devices share the same conformance to performance standards and both function as RF surgery units.

Based on the information supplied in this 510(k), we conclude that the subject devices are safe, effective, and substantially equivalent to the predicate devices.

Holger Söring
General Manager
Söring GmbH
Medizintechnik
Justus-v.Liebig 10
25451 Quickborn
Germany

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1999

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

Re: K993265
Trade Name: Soring GmbH, ARCO 3000, ARCO 2000, ARCO 1000, MBC 601, MBC 600
Regulatory Class: II
Product Code: GEI
Dated: July 28, 1999
Received: September 29, 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: K993265

Device Name: Soring GmbH, ARCO 3000, ARCO 2000, ARCO 1000, MBC 601 and MBC 600

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ 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 K993265