JAN 1 7 2003

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

K030028

Date Prepared:

28 December 28, 2002

Submitter's Information:

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

Trade Name, Common Name, Classification:

Trade name:	Soring GmbH CPC™ devices
Common name:	Electrosurgical conductive gas coagulation
Classification name:	878.4400 - Device, Electrosurgical, Cutting & Coagulation & Accessories

Predicate Device:

Name:	Söring GmbH, ARCO 3000, ARCO 2000, ARCO 1000, MBC
510(k) Number	K993265
Regulation Number	878.4400 - Device, Electrosurgical, Cutting & Coagulation & Accessories
Product Code	GEI
Decision Date	10/22/1999

Device Description:

During the use of RF surgery devices, power is transmitted via an electrode in the contact zone to tissue. When RF energy reaches a certain upper limit, an arc will occur at the contact zone of the active electrode to the tissue. This leads to a quick warm-up of the intercellular fluid. This vaporization of the intercellular fluid results into a burst of the cells and the tissue looses its cohesion, the electrode then cuts. Lower RF-voltages (below 150veff) lead to a slower heat-up of the tissue, resulting in coagulation with no separation. Short RF-impulses with high voltage lead in a build-up of sparks together with a strong surface coagulation.

Cold plasma technology using Helium gas is a very gentle method for coagulating or dissecting specific types of tissue. In contrast to conventional RF surgery, the penetration depth related to tissue damage and the electrical strain on the patient are significantly reduced (no electrical current flowing through the patient). The significantly lower peak current value (as compared to conventional spray coagulation) results in far less damage to tissue layers immediately beneath the treatment area because constant sine-shaped currents are used.

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Indications for Use:

The devices are intended to cut and or coagulate soft biological tissue with gas-enhanced coagulation during general surgical procedures. Typical users of this system are trained medical professionals.

Performance Data:

The Soring GmbH CPC™ devices and predicate devices both use standard data communications controls to detect errors. Both devices comply 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

Conclusion:

Similar to the predicate device, the Soring GmbH CPC™ devices do not control any life sustaining functions or services. The new 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Soring GmbH Medizintechnik
c/o Mr. Carl Alletto
President
Delta Quality Consulting
1100 Lakeview Boulevard
Denton, Texas 76208

Re: K030028
Trade Name: Soring GmbH CPC™ Devices
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: January 3, 2002
Received: January 3, 2002

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

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

Enclosure

(Indications for Use Form)

510(k) Number:

Device Name: Soring, CPC™ devices

Indications for Use:

The devices are intended to cut and or coagulate soft biological tissue with gas-enhanced coagulation during surgical procedures.

Typical users of this system are trained medical professionals.

(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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030028