510(k) Summary of Safety and effectiveness.

K023733

Submitter:

MAY 1 4 2003

Ingenjörsfirman Björn Bergdahl AB
Hällesås byväg 31
427 51 Billdal
Sweden

Contact person:

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Device:

***Coa-Comp/M* Automatic Bipolar Coagulator**. Class II device.

For coagulation of soft tissue during surgery using Radio Frequency, a pure sine-wave with frequency 512 kHz. Maximum power output 40W into 100 Ohms.

The device has same characteristics and data as predicate devices: CBC-1 Coa-Comp Anti Sticking Bipolar Coagulator and CBC-2 Bipolar Coagulator, Radionics Inc, 22 Terry Ave. Burlington, MA 01803, USA. K870149 and K870177. Those devices were manufactured by Ingenjörsfirman Björn Bergdahl AB, (address as above).

B. Bergdahl

Björn Bergdahl

2003-05-02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 4 2003

Mr. Björn Bergdahl
Ingenjörsfirman Björn Bergdahl AB
Hällesås byväg 31
427 51 Billdal
Sweden

Re: K023733
Trade/Device Name: Coa-Comp/M Automatic Bipolar Coagulator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 9, 2003
Received: February 19, 2003

Dear Mr. Bergdahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

2003-05-02

510(k) Number K 023733

Device Name: Coa-Comp/M Bipolar Coagulator.

Indications For Use:

Coagulation of soft tissue during surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023733