

K972071

510(k) Notification
BOVIE Model X40 Electrosurgical Generator

May 30, 1997

OCT 21 1997

SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS

For more than 50 years, high-frequency (HF) surgery has been used to cut and/or coagulate biological tissue using the intrinsic thermal effect of electric current. Berchtold has produced a state-of-the-art electrosurgical generator for international distribution. The BOVIE Model X40 represents one of the latest of these instruments. It is based upon Berchtold's long standing commitment to the provision of high quality surgical equipment and is produced in accordance with established international standards for such instruments.

In order to protect the patient and user from inadvertent injury from the use of this instrument it is provided with several safety features. These include:

Self checking software which performs an automatic safety check each time the instrument is turned on.

Real time, continuous monitoring of the patient contact with the neutral electrode.

Automatic detection of the use of split or single plate neutral electrode.

Automatic monitoring of HF leakage current and non-programed output.

Automatic detection and display of malfunction.

State-of-the-art control panel with audio (spoken) verification of unit function and confirmation of foot or finger switch activation.

Automatic cut-off to prevent excess tissue over-heating and electrode sticking.

Automatically adjusted output to ensure the cutting power is maintained at the minimum level required to effect the cut as tissue characteristics or electrode geometry change.

We believe the above mentioned safety features, and the test results obtained and included in this 510(k) Notification demonstrate that the BOVIE Model X40 is safe and effective for its intended use.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Michael A. Clark
South East Regulatory Associates, Inc.
1070 Thornwood Lane
Dacula, Georgia 30211-3007

OCT 21 1997

Re: K972071
Trade Name: BOVIE Model X40
Regulatory Class: II
Product Code: GEI
Dated: September 8, 1997
Received: September 10, 1997

Dear Mr. Clark:

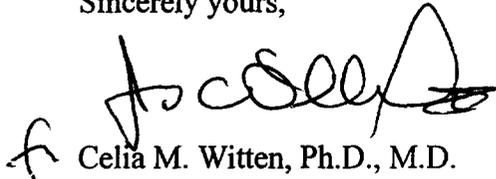
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

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

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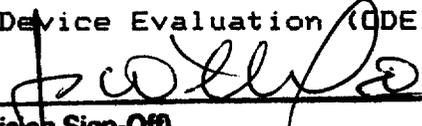
INDICATIONS FOR USE

The BOVIE Model X40 Electrosurgical Generator is Indicated for Use in laparoscopic surgical procedures for the cutting and coagulation of human tissue.

The BOVIE Model X40 can be used in conjunction with the appropriate accessories and instruments for applications in:

- General Surgery
- Gynecology
- Urology
- Gastroenterology

Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K972071

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____