AUG - 5 2004

K030819

510(k) Summary

October 30th 2003

1 Submitter

Plasma Surgical Ltd
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2 Name of Device

Proprietary Name: PlasmaJet™ system, comprising:

a) PlasmaJet™ console
b) PlasmaJet™ service module
c) PlasmaJet™ open surgery handpieces
d) PlasmaJet™ laparoscopic surgery handpieces

Common Name: Neutral Plasma Coagulator

Device Classification: Electrosurgical coagulation devices have been placed in Class II as per 21 CFR Regulation Number 878.4400 and assigned the Product Code GEI.

3 Predicate Devices

The components of the PlasmaJet™ system are substantially equivalent to the following legally marketed devices:

K871435	Bard EMS System 6000
K904545	Valleylab Force GSU™ System / Force GSU™ Handset
K963189	Erbe APC300 Argon Plasma Coagulator and Accessories

This statement is based on the similarity of the subject device to the predicate devices in intended use, materials, design and principles of operation.

4 Device Description

The PlasmaJet™ system consists of a range of single-use open or laparoscopic handpieces that are used for coagulation using neutral argon plasma. A console is used to power the handpiece and a footswitch and a service module (providing a convenient base and housing for an argon tank) completes the system.

In the PlasmaJet™ system, as in a bipolar electrosurgery system, both anode and cathode used to generate the argon plasma are contained within the handpiece, and no ground plate is used. Because both electrodes are located within the enclosure of the handpiece there is no current flow through the patient and no risk of alternate site burns. In the PlasmaJet™ handpiece, a specially designed series of electrodes allows a relatively low voltage (of about 30V) to generate a more energetic and extensive argon plasma than that used in an argon beam coagulator. The PlasmaJet™ plasma uses a much lower flow of argon gas than is used in the argon beam coagulator; the plasma is electrically neutral and comprises a mixture of excited argon atoms, argon ions, and electrons that emerge from the tip of the handpiece in an intense pale blue jet or beam.

When the plasma jet reaches the bleeding tissue, it gives up its kinetic energy as heat and causes coagulation of the bleeding surface by a series of processes. First, the physical force of the flowing stream of argon plasma removes liquid blood from the tissue surface or vessel. Secondly, the energy dissipated from the plasma to the tissue desiccates the tissue to form a series of layers of eschar that seal the tissue surface and prevent further bleeding.

5 Intended Use

The PlasmaJet™ system is a neutral plasma coagulator that is designed for coagulation in open surgery and laparoscopic surgery.

6 Summary of Substantial Equivalence

The PlasmaJet™ system is similar in design, intended use and performance characteristics to the predicate devices. It differs in combining the electrodes used to generate argon plasma within the handpiece, and does not require the use of an electrosurgical grounding plate, nor does a current pass through the patient as in conventional electrosurgery or argon beam coagulation. Animal and clinical studies have been performed and these have established that the neutral plasma coagulator provides more effective coagulation than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Professor Peter F. Gibson
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First Floor
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London W1X 3HF
United Kingdom

Re: K030819
Trade/Device Name: PlasmaJet™ System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 25, 2004
Received: May 27, 2004

Dear Professor Gibson:

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. 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

510(k) Number (if Known): K030819

Device Name: PlasmaJet™ System

Indications for Use: The PlasmaJet™ System is a neutral plasma coagulator that is designed for coagulation in open surgery and laparoscopic surgery.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFGR 801 Subpart C)

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Miriam C Provost

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

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