K121977

PLASMA SURGICAL

510(k) Summary

for the Plasma Surgical PlasmaJet® System (Version 3-Plus)

NOV 20 2012

November 19th 2012

1 Submitter

Plasma Surgical Ltd
127 Milton Park
Abingdon
Oxfordshire
OX14 4SA
United Kingdom

Contact Person: Peter F Gibson
Telephone: +44 1235 822506
Facsimile: +44 1235 820832
E-mail: pgibson@plasmasurgical.com

2 Name of Device

Proprietary Name: PlasmaJet® system, comprising:

a) PlasmaJet® console (Version 3-Plus)
b) PlasmaJet® service module
c) PlasmaJet® open surgery handpieces
d) PlasmaJet® laparoscopic surgery handpieces

Common Name: Neutral Plasma Surgery system

Device Classification: Electrosurgical cutting and 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:

K080197	Plasma Surgical PlasmaJet® Neutral Plasma Surgery System
K031085	Gyrus PlasmaKinetic Superpulse Generator System & Accessories
K100415	Lumenis AcuPulse 30/40ST and 40WG CO_2 Laser Systems

4 Intended Use

The PlasmaJet® system is a neutral plasma surgery system that is designed for cutting, coagulation and the removal of soft tissue by vaporization in open surgery and laparoscopic surgery.

5 Comparison to Predicate Devices

The PlasmaJet® system that is the subject of this submission is identical in technological characteristics to the predicate PlasmaJet® device (K080197). The new handpieces with optimized performance for the subject PlasmaJet® system are similar in design, materials and construction to the handpieces of the predicate PlasmaJet® device and employ the same plasma energy source. They differ only in the internal dimensions of the electrode group to provide a more fine plasma stream and that is optimised for most effective use with rapidly pulsed plasma. The latest version of the PlasmaJet® console (Version 3-Plus) features rapidly pulsed plasma in a so-called "Ultra" mode that provides optimal cutting and coagulation capability. A user selectable pulse mode was present in the predicate PlasmaJet® device.

In its ability to cut and remove tissue, the action of the PlasmaJet® system is similar to that of the predicate Gyrus PlasmaKinetic Superpulse electrosurgery system (K031085) and the Lumenis AcuPulse CO_2 laser (K100415). However, the energy of the plasma stream from the PlasmaJet® falls rapidly with distance and allows the surgeon to control the surgical effect by adjusting the distance to tissue.

6 Summary of Substantial Equivalence

Pre-clinical and tissue studies have been performed and these have established that the PlasmaJet® neutral plasma surgery system provides safe and effective cutting, coagulation and removal of soft tissue by vaporization equivalent to predicate devices with minimal damage to underlying tissue.

Plasma Surgical Limited
127 Milton Park, Abingdon, Oxfordshire
OX14 4SA, United Kingdom
Telephone: +44 (0)1235 822500 Facsimile: +44 (0)1235 820832
Registered in England No. 3709815

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Plasma Surgical Limited
% Dr. Peter Gibson
Senior Vice-President
127 Milton Park
Abingdon, Oxfordshire
United Kingdom OX14-4SA

November 20, 2012

Re: K121977
Trade/Device Name: PlasmaJet® Neutral Plasma Surgery System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 13, 2012
Received: November 14, 2012

Dear Dr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K121977

Device Name: PlasmaJet® System

Indications for Use: The PlasmaJet is a neutral plasma surgery system that is designed for cutting, coagulation and the removal of soft tissue by vaporization 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)

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Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K121977