CANADY TECHNOLOGY

510(k) Summary

AUG 3 1 2005

510(k) Summary of Safety and Effectiveness for Canady Argon Plasma Probes

K052035

Submitted By: Canady Technology LLC
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Date Prepared: 07.01.2005

Common Name: Electrosurgical Argon Beam Probe

Trade Name: Canady Plasma Probes for flexible Endoscopy
- Canady Plasma GIT Probe
- Canady Plasma TBS Probe

Classification Name: Electrosurgical cutting and coagulation device and accessories (21CFR878.4400)

Product Code: 79 GEI

Predicate Devices:
- Erbe APC Applicators: K#963189, cleared Nov. 26, 1996
- Erbe APC Applicators: K#013348, cleared Oct. 26, 2001
- Conmed ABC Flex Probes: K# 990586, cleared May 17, 1999

Device Description:

The Canady Plasma Probes are tubular instruments and are flexible. They are provided in various lengths and diameter sizes to accommodate the various size/types of endoscopes for a variety of applications (i.e. the treatment of various target tissues inside a patient). The Probes have applications in endoscopic surgical procedures such as upper and lower gastroenterology and bronchoscopy to provide a means of coagulation using electrosurgical current and argon gas.
The device consists of a connector which acts also as a handle for maneuvering the probe inside the working channel of an endoscope. Via an inner lumen of the Canady Plasma Probe argon gas is delivered to the operative site as well as an internal wire to carry high frequency (HF) electrosurgical current to a tungsten electrode tip at the end of the tubing. A ceramic tip insulates the thermal plastic tubing from the heat generated during coagulation. The electrode is positioned in the ceramic tip such that it cannot contact the patient's tissue during coagulation procedure.

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The Canady Plasma Probes are provided sterile by means of ethylene oxide and are disposable (Single Use)

Application
An endoscope is manipulated inside the patient to locate tissue that requires treatment. Upon finding the target tissue, the Canady Plasma Probe is threaded into the working channel of the endoscope, until the tip of the Probe slightly protrudes from the end of the scope. Then opening of the Probe is positioned towards in close proximity of the area to be treated. The Canady Plasma Probes have depth marker rings close to the tip for positioning purposes. When high frequency voltages reaches the certain level and the proximity to tissue is close enough, electrically conductive argon plasma forms in the gas stream. This allows the current to flow between the probe and the tissue. Current density upon arrival at the tissue surface from an APB probe (Argon Plasma Beam) causes coagulation. The application of the energy to the tissue is uniform and contact free. Canady Plasma Probes are for single use only.

Intended Use:
The Canady Plasma Probes' intended use is for the delivery of argon gas plasma energy for argon enhanced coagulation of tissue.

Electrical Characteristic:
Canady Plasma Probes can be operated in combination with HF generators which are compatible to the connector hose cleared under K#013348 to a

max. HF voltage of 4.0 kVp / max. HF power of 50 W	for the TBS probes
max. HF voltage of 4.3 kVp / max. HF power of 90 W	for the GIT probes (2.3 mm)
max. HF voltage of 4.3 kVp / max. HF power of 120 W	for the GIT probes (3.2 mm)

Dimensions:
The lengths of the Canady Argon Probes are 1.6 m (5.2 ft) to 3.4 m (11 ft). The diameters of the probes are 1.5 mm (4.5 Fr) to 3.2 mm (9.6 Fr).

Similarities to Predicate Devices:
The Canady Plasma Probes have the same performance specifications and intended use like the predicate devices. They are also provided sterile by ethylene oxide and are disposables for single use only. The connector is compatible in function to the connector of the probe which is cleared in K#013348 and also compatible to the corresponding connector hose.
The tube diameters and lengths are very similar. Both, the Canady Plasma Probes and the predicate devices have marking rings at the distal end (scaled probe tip). Also the used materials – which is ceramic at the distal end and Teflon for the tubes of the probes - are identical. In consequence the insulation characteristic is the same. The electrical characteristics are one and the same.

Differences to Predicate Devices:
The connectors of the predicate devices K#990586 and K#963189 are different.

Conclusions:
Canady Plasma Probes are substantial equivalent in its Intended Use, Dimensions, Used Materials, Construction, Quality, Electrical Characteristics, Operational Principles and Labeling to the legally marketed devices to which the Canady Plasma Probes are compared in this submission.

The differences do not affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Canady Technology, LLC
c/o Mr. Stefan Preiss
TPR Project Manager
TUV America Inc., TUV Product Service
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K052035
Trade/Device Name: Canady Plasma Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 17, 2005
Received: August 22, 2005

Dear Mr. Preiss:

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 (240) 276-0115. 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,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K052035

Device Name: Canady Plasma Probe

Indications for Use:

Argon Enhanced Coagulation of Tissue

Prescription Use X
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MXM

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

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