K103375

510(K) SUMMARY

MEDTEK DEVICES, INC

MAR 16 2011

PLUMEPEN® INTEGRATED SMOKE EVACUATION PENCIL

SUBMITTER/510(K) HOLDER

Name:	MEDTEK DEVICES, INC., dba Buffalo Filter
Address:	595 Commerce Drive Amherst, New York 14228
Contact Person:	Greg Pepe
Telephone:	716-835-7000
Prepared:	September 14, 2010

DEVICE NAME

Proprietary Name:	PLUMEPEN
Common/Usual Name:	Electrosurgical Pencil Accessory for Surgical Smoke Evacuation
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories

Predicate Devices

MEDTEK DEVICES, INC. (" Medtek") claims substantial equivalence to:

1. Conmed Corporation. Conmed GoldVac Integrated Smoke Evacuation Pencil (K081634)
2. I.C. Medical, Inc. Telescoping PenEvac (K954088)
3. Buffalo Filter Co., Inc. PenAdapt (K000904)
4. E & M Engineering, Inc. Electrosurgical Pencil (k936304)

Device Description

The PLUMEPEN Integrated Smoke Evacuation Pencil is a sterile, single use integrated electrosurgical pencil and smoke evacuation handpiece. The device is intended for general

electrosurgical applications and when used in conjunction with an effective smoke evacuation system, for removing smoke generated by electrosurgery.

The integration of smoke evacuation and electrosurgery allows for operator to deliver the electrosurgical current from the generator and capture the smoke plume with a single device. Surgical smoke plume is a potentially dangerous by-product generated from electrosurgery. The primary health risk is inhalation of surgical smoke. As this device cauterizes vessels and destroys (vaporize) tissue, fluid, and blood create a gaseous material known as smoke plume. The amount, content, and particulate size of smoke plume can vary depending on the type of procedure and surgical technique. Research regarding surgical smoke produced from electrosurgery has shown to contain viable viruses, bacteria, blood, blood fragments, carcinogens and neuro-toxic compounds. The traditional surgical mask has been determined to be not adequate for personal protection. The Occupational Health and Safety Administration has issued recommendations that surgical smoke be removed and properly filtered by a smoke evacuation system as close to the surgical site as possible.

The device is constructed using the same materials and design specifications commonly found in the predicate devices in the electrosurgical marketplace. The device is designed to integrate smoke evacuation into electrosurgery by combining both features into a single handpiece. The integrated smoke evacuation pathway is located above the electrosurgical blade to capture the smoke plume created during cauterization. Studies have shown that surgical smoke rises after generation, so the placement of the channel above the blade has demonstrated superior capture effectiveness. The extendable channel allows for adjustment of the capture position to accommodate a variety of different style and length electrosurgical blades. There are two (2) buttons on the device, which activate monopolar cut or coagulate. The pencil is connected to tubing which will be attached to a variety of smoke evacuation systems. The smoke is then filtered by the smoke evacuation system to limit personnel exposure to the hazards associated with surgical smoke plume. The device will be packaged singly for sterile distribution.

Intended Use

The PLUMEPEN is designed for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Indications for use for PLUMEPEN® Integrated Smoke Evacuation Pencil include:

a. To remove smoke plume from the surgical site

b. To remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect

Technological Characteristics And Substantial Equivalence

Substantial equivalence is based on four (4) predicate devices. All the above referenced predicates are Electrosurgical Cutting and Coagulation Device and Accessories; and Air-handling apparatus for a surgical operating room as defined in 21 CFR § 878.4400 and 21 CFR § 878.5070 respectively.

The Medtek Devices PLUMEPEN is an integration of two technologies, electro surgery and smoke evacuation, previously cleared for use in predicate devices into a single device. The main difference from a standalone electrosurgical handpiece is the integration of a smoke capture channel into the main body. This smoke capture channel is designed to be placed in a variety of positions, near the tip of the electrode for maximum smoke capture or retracted back for maximum accessibility and visibility. The location of the smoke evacuation channel above the electrode in the handpiece allows for maximum capture potential, as studies have shown the surgical smoke travels upward from the point of generation.

The tubing houses the cord set for a length to eliminate clutter in the surgical field and the back end of the pencil swivels to allow for maximum range of motion with limited drag.

Like all the predicate devices, the PLUMEPEN is used in hospitals, operating room theaters and requires physician's prescription for use. The external anatomical sites for the patient contact appliance are similar for all devices- open body parts.

The technological characteristics of the electrosurgical handpiece do not change compared with the predicate devices; cut, coagulate and smoke evacuation remain contained in one device. The PLUMEPEN utilizes the same electrosurgical pencil as the predicate device, 'Electrosurgical Pencil' but like all other predicate devices, Medtek has integrated the smoke channel for evacuation of surgical smoke. The PLUMEPEN is equivalent in operational characteristics to the predicate devices, GoldVac, PenEvac and PenAdapt in that, cut, coagulate and smoke evacuations are contained in one device, limiting the need for several devices present at the surgical site that perform these functions independently of each other. Like the predicate devices, the PLUMEPEN enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the target tissue for the desired surgical effect.

PLUMEPEN has made no changes to the generator and therefore no changes to the accompanying software, compared to the predicate devices. Like the predicate device GOLDVAC, the generator provides alarms for conditions that could pose a risk to the patient and the operator sets the appropriate mode and output settings for the device.

Performance Testing

Bench testing on the subject device has shown the device to perform as intended with the same or similar results as a predicate device. No particular requirements specific to this smoke performance exist in the standards but tests conducted with the device have shown no effect or changes to the function of the electrosurgical pencil. The nozzle or intake portion of the device

has been designed so as to not impede the operation of the electrosurgical function of the pencil and provides for intake of the surgical smoke for filtering.

Non Clinical Testing

PLUMEPEN and all the predicate devices, except PenAdapt, use 'ABS plastic' for the body of the device. The PLUMEPEN uses previously cleared stainless steel blade (K936304) in its model PLP 1000 and previously cleared non stick blade (K043036) in its model PLP 2000. The predicate devices, Electrosurgical Pencil, GoldVac and PenEvac also use stainless steel and non stick blades. The predicate devices use polycarbonate for the smoke tube or smoke channel, the PLUMEPEN uses a higher quality, similar material as polycarbonate called K- resin (SBC) for its smoke tube. The PenAdapt uses Silicone elastometer.

The proposed device is equivalent to the identified predicate devices with respect to technological characteristics and function. The device has been designed to comply with the applicable sections of the International Electrotechnical Commission (IEC) Standard for Electrosurgical Devices, 60601-2-2 and Biocompatibility standard ISO 10993. In addition to these standards, the predicate devices GoldVac and PenEvac also comply with ANSI/AAMI HF-18 standard. But IEC 60601-2-2 was approved by American National Standards Institute (ANSI) as a revision of ANSI/AAMI HF-18, Electrosurgical devices, on November 2, 2006. Therefore, PLUMEPEN's compliance with ANSI/AAMI HF-18 standard is not required.

The design, operational and technical characteristics, performance and non clinical testing of the PLUMEPEN® Integrated Smoke Evacuation Pencil are substantially equivalent to and as effective as that of the predicate devices. The PLUMEPEN is as safe and performs as well as or better than the previously identified legally marketed predicate devices. The PLUMEPEN's intended use and indications statement for use are substantially supported by the previously cleared predicate devices; and do not impact the safety and effectiveness of the device when used as labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MEDTEK DEVICES, INC., dba Buffalo Filter
% Regulatory Technology Services LLC
Mr. Mark Job
1394 25th Street NW
Buffalo, MN 55313

MAR 16 2011

Re: K103375
Trade/Device Name: PLUMEPEN® Integrated Smoke Evacuation Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 28, 2011
Received: March 1, 2011

Dear Mr. Job:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

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Prescription Use X AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103375