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K060183

510K SUMMARY

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Contact Person: John Tartal

Date Prepared: 01/23/06

Common Name: Argon Plasma Coagulation (APC) Integrated Filter Probes and Adapter

Trade/Proprietary Name: ERBE APC Integrated Filter Probes and Adapter

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

Product Code: GEI

Legally Marketed Device: APC Connector Hose and Probes submitted in the ERBE 510(k) Number K013348 as well as APC Membrane Filter (as an Accessory) in ERBE 510(k) Number K024047

Note: The APC Integrated Filter Probes and Adapter are being submitted in this premarket notification are modified from the accessories in the above 510(k)s. The modifications were determined to require a 510(k) submission.

Device Description:

The APC Integrated Filter Probes incorporate a filter similar to the APC Membrane Filter and the hose (specifically the length) of an APC Connector Hose into one device. See Section IV, Appendix 1, Product Pictures (IV-2). The Probes are flexible. They are provided in various lengths, diameter sizes, and tip configurations 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 working lengths (i.e., the segment of the Probe that would go down a scope) of the APC Integrated Filter Probes are 4.9ft. (1.5m) to 9.8ft. (3m). The working diameters of the Probes are 4.5 French (1.5mm) to 9.6 French (3.2mm). The Probes have either an axial (straight fire), lateral (side fire), or circumferential opening allowing the energy to be delivered straight, at a 45 to 90 degree angle, or directly to target tissue regardless of the probe's position. The three types of openings for the APC Integrated Filter Probes allow the physician a choice in the direction or the option not to have to consider the direction (just proximity) of delivering the argon plasma to the treatment site which is based upon tissue resistance.

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Note: Since the last 510(k), two (2) additional APC Probes became apart of the product line. The modifications were insignificant. One involved a different outer diameter and length, but the changes were within the ranges of dimensions that were already included in approved Probes. The other involved modifying the tip of a side fire probe for circumferential application. Besides the modification to the tip shape, the bonding material changed to Vitadur Alpha. However, the material difference in the tip did not raise any biocompatibility issues.

For each Probe, the blue connector/filter end is made of plastics (including the membrane filter) with brass contact pins coated with nickel. The filter is 0.45 µm and protects the Argon Plasma Coagulator (the Equipment) from contamination if there is a backflow of blood or any other fluid contaminant. The hose part of the Probe is made of Teflon (PTFE). Finally, the tube portion of the Probe is made of polyurethane, PTFE and a stainless steel wafer shape electrode close to the tip for terminating electrical current. Various glues/adhesives are used to secure all of the Probe's parts. Ceramic tips are bonded on the APC Integrated Filter Side Fire and Circumferential Probes. Functionality and reliability of the Probes were demonstrated through validation testing using Recognized Standards. All added or modified materials in the APC Integrated Filter Probes were evaluated for biocompatibility with no problem found (See Section III, Biocompatibility, III-10 to III-19).

The APC Integrated Filter Probes are provided sterile by means of ethylene oxide and are disposable (Single Use) [Note: The sterilization cycle has been validated. See Section III, Sterilization Information, III-20.].

The APC Integrated Filter Probe Adapter is a flexible connecting cable. See Section IV, Appendix 1, Product Pictures (IV-3). It connects the APC Integrated Filter Probe to an ERBE Argon Plasma Coagulator. The Adapter is a conduit for both electrosurgical current and argon gas. It is approximately 13-1/2" in length. The connector ends of the Adapter are made of plastics. The cable portion of the Adapter is silicone. The Adapter's performance was validated via Recognized Standards. The APC Integrated Filter Probe Adapter is provided non-sterile and is reusable (Note: The Adapter only needs to be externally cleaned/disinfected unless it is contaminated.).

The APC Integrated Filter Probes and Adapter are accessories of the ERBE Argon Plasma Coagulator Models APC 300 and APC 2 [Note: The Coagulator is used with an associated ERBE ElectroSurgical Unit (ESU)]. The APC Integrated Filter Probe Adapter attaches to gas as well as electrical inputs of the Coagulator and then to an APC Integrated Filter Probe [Note: It is possible to connect an APC Integrated Filter probe directed to ERBE Coagulator APC 2 Model if it has an FiAPC Receptacle). An endoscope is manipulated inside the patient to locate tissue that requires treatment. Upon finding the target tissue, the Probe is threaded into the working channel of the endoscope, until the tip of the APC Integrated Filter Probe slightly protrudes from the end of the scope. The opening of the Probe is positioned towards/in close proximity of the area to be treated (Note: The APC Integrated Filter Probes have depth marker rings close to the tip for positioning purposes.). The APC/ESU system is activated via a

footswitch. When high frequency voltage reaches the critical 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 causes coagulation. The application of the energy to the tissue is uniform and contact free.

Intended Use:

The APC Integrated Filter Probes are intended for use in Argon Plasma Coagulation (APC). The devices are used to treat many conditions in endoscopy for various surgical procedures.

Note: The APC Integrated Filter Probe Adapter is just the attachment piece to connect an APC Integrated Filter Probe to an ERBE Coagulator Model APC 300. The Adapter is only needed for the ERBE APC 2 Model if a FiAPC Receptacle is not installed.

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

APC Integrated Filter Probes and Adapter

Similarities
The APC Integrated Filter Probes have the same performance, working dimensional and tip specifications (i.e., working diameter and lengths as well as tip configurations), intended use, labeling, and packaging specifications as the predicate APC Probes. The APC Integrated Filter Probes incorporate a filter similar to and performs like the predicate APC Membrane Filter. Also like the predicates, the Filter Probes are provided sterile by ethylene oxide and are single use. Furthermore, the hose length of the APC Integrated Filter Probes is the same as the APC Connector Hose. Like the predicate APC Probes, the APC Integrated Filter Probes have an instrument recognition system. If attached directly into an ERBE Argon Plasma Coagulator Model APC 2 via an FiAPC receptacle, the Coagulator recognizes the Probe diameter size and automatically sets conservative default settings.

The APC Integrated Filter Probe Adapter is basically the connectors of the APC Connector Hose. The connectors that attach to an ERBE Coagulator are the same as the connectors on the APC Connector Hose. The APC Integrated Filter Probe Adapter has the same type of materials (plastics and silicone), performance specifications, intended use, labeling, and packaging specifications as the predicate APC Connector Hose. Also like the predicate, it is provided non-sterile and is reusable.

Differences
The APC Integrated Filter Probes have a different connector end as well as incorporates a filter and length of hose (Note: Due to having the filter at the end of the Probes, the connector was modified. This was also done so that it only fits its designated Adapter.). The structural modifications of changing the connector end didn't

raise any safety or efficacy issues. The connector fits snugly on the designated Adapter (i.e., the conduit to the ERBE Coagulator). Also no negative impact was found with the dimensional modification of including a filter and the hose in the Probes. The filter in the Probe is 0.45 µm as compared to the stand alone APC Membrane Filter size being 0.2 µm. The larger pore size was found to be sufficient in keeping backflow fluid from reaching the Adapter or Coagulator. The slight materials changes (i.e., in plastics, the metal, and/or in glues) were found to be acceptable in producing a functionally reliable Probe. The instrument recognition system in the APC Integrated Filter Probes are chipped (EPROM) based as compared to the predicate APC Probes which are recognized via resistors. The chipped based recognition system is more specific and can provide more information. Finally; slightly different plastics, metals, and adhesives were used in the APC Integrated Filter Probes in comparison to the predicate APC Membrane Filter, Probes, and Connector Hose. The materials were found via validation testing and applied Recognized Standards to work well in the APC Integrated Filter Probes and the materials are biocompatible. See Section III, Biocompatibility and Summary of Design Control Activities.

The APC Integrated Filter Probe Adapter is different that the APC Connector Hose in that it doesn't have the hose portion and the connector to the Probe was modified so it only attaches to the APC Integrated Filter Probes. The dimensional modification of not having the hose portion and the structural modification to the end that connects to the APC Filter Probes do not raise any safety or efficacy concerns for the Adapter. The APC Integrated Filter Probe Adapter connects snugly to the Filter Probes. It was also found to function properly through validated testing and using Recognized Standards. The Adapter is also different that the predicate APC Connector Hose in that the Adapter has a resistor instrument recognition system. If the Adapter is used, it overrides specific probe recognition. However, no safety or efficacy issues are expected because the Adapter's resistor sets the lowest/most conservative default settings (i.e., gas flow and wattage) on an ERBE Coagulator. As a result for the Probe being used, the settings adjustments on the ERBE Coagulator would only be upward. Setting maximums for the gas flow rate and wattage are specified for each APC Probe in the Notes On Use (NOU) for the Probes. In the "How to Use" section of the NOU, the user is also directed to setting limitations and instructed not to exceed maximums for the APC Probe being used. If the gas flow rate limit is appreciably exceeded when using the Adapter and the smallest diameter APC Probe, then the Coagulator errors preventing activation. With the Adapter and the largest diameter APC Probe the maximum gas flow rate is limited: however, no problem with in the clinical environment is expected. Typically, desired settings are established during test firing of the Probe. Therefore, no problems in regards to not having specific probe recognition are expected. Biocompatibility testing was not necessary because the Adapter doesn't come in contact with the patient.

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Note: Incorporating the filter in the Probes eliminates the need to reprocess the Adapter between cases as compared with the APC Connector Hose because backflow contamination can not reach the Adapter or Coagulator.

All the changes have been verified or validated in design control.

Conclusion:

The APC Integrated Filter Probes and Adapter have the same intended use, principles of operation, and technological characteristics as the accessories in the previously cleared predicate devices. None of the changes/modifications were found to have a safety or efficacy affect on the APC Integrated Filter Probes and Adapter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2006

Mr. John Tartal
Manager
Quality Assurance and Regulatory Affairs
ERBE USA, Inc.
2225 Northwest Parkway
Marietta, Georgia 30157

Re: K060183
Trade/Device Name: ERBE APC Integrated Filter Probes and Adapter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 23, 2006
Received: January 25, 2006

Dear Mr. Tartal:

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" (21 CFR 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/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting 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): K060183

Device Name: ERBE APC Integrated Filter Probes and Adapter

Indications for Use:

Argon Plasma Coagulation (APC)

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Division of General, Restorative, and Neurological Devices

510(k) Number_____