March 14, 2019

GENICON, Inc.
Ms. Katlyn Kachman
Director of Quality and Regulatory Compliance
6869 Stapoint Court
Suite 114
Winter Park, Florida 32792

Re: K190168
Trade/Device Name: GENICON Aquas Probes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 23, 2019
Received: January 31, 2019

Dear Ms. Kachman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.03.14 10:49:57 -04'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190168

Device Name
GENICON Aquas Probes

Indications for Use *(Describe)*
The GENICON Aquas Probes are instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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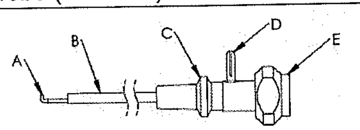
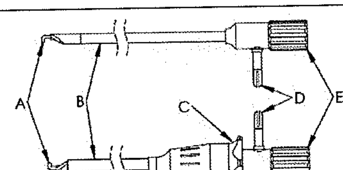
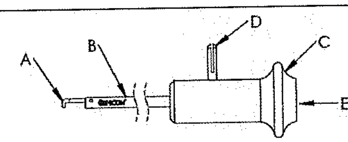
K190168
510(k) Summary

1. Contact Information
   GENICON
   6869 Stapoint Court, Suite 114, Winter Park, FL 32792
   Phone (407) 657-4851 Fax (407) 677-9773
   Katlyn Kachman, Director of Quality
   January 23, 2019

2. Device Name
   - Trade Name – GENICON Aquas Probes
   - Common Name – Monopolar Electrode, Electrocautery Probe, Electrosurgical Probe
   - Classification Name – Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400, Product Code GEI)

3. Substantially Equivalent Device
   Legally Marketed (unmodified) Devices: Stryker Stiletto Electrosurgical Probe, K052141
   Pajunks HF Electrodes, K062047

Device	Stryker Stiletto Electrosurgical Probe (K052141)	Pajunks HF Electrodes (K062047)	GENICON Aquas Probes
Component Design	 A. Electrosurgical Tip B. Insulation C. Insulation Control Knob D. HF Post E. Handle	 A. Electrosurgical Tip B. Insulation C. Insulation Control Knob D. HF Post E. Handle	 A. Electrosurgical Tip B. Insulation C. Insulation Control Knob D. HF Post E. Handle
Design	The Stryker Stiletto Electrosurgical Probe is a suction/irrigation probe with electrosurgical capability indicated for use in laparoscopic surgical procedures. The device allows for suction and irrigation of sterile irrigant solution. In addition, the device is intended to be used for electrosurgical cutting/coagulation during laparoscopic procedures. Products include optional retractable insulation and are also provided without the suction/irrigation functions.	The Pajunk adaptable and retractable HF Electrodes are multiple use, non-sterile delivered and latex free medical devices. The instruments are insulated for optional monopolar coagulation which enables a surgeon to manipulate, dissect, retrieve, biopsy, cut, or coagulate internal tissue or organs while performing laparoscopic procedures. Pajunk provides electrodes with and without suction and irrigation element and electrodes with suction and irrigation capacity with retractable/extendable tips.	The GENICON Reusable Electrosurgical Probes are multiple use, non-sterile delivered medical devices. The instruments are insulated for optional monopolar coagulation which enables a surgeon to manipulate, cut, or coagulate soft tissue or organs while performing laparoscopic procedures. GENICON provides electrodes with and without suction and irrigation element and electrodes with suction and irrigation capacity with retractable/extendable tips.
Diameter	5 mm	5 mm	5 mm
Working Length	33 to 45 cm	34 to 44 cm	20 to 45 cm
Electrosurgical Tips	Spatula, L-Hook, J-Hook, Ball, Needle, Spoon	Spatula, L-Hook, J-Hook, Knife, Needle, 45 Deg	Spatula, L-Hook, J-Hook, Knife, Needle, 45 Deg

Materials	Stainless Steel, Polyimide, PTFE, Silicone, Rubber	Stainless Steel, Polyamide or Ceramic	Stainless Steel, PEEK, POM, PPSU, PTFE/FEP, Silicone
Testing	Electrical and mechanical performance of the predicate devices were evaluated and benchmarks established.	Electrical and mechanical performance of the predicate devices were evaluated and benchmarks established.	Performance of the GENICON Reusable Electrosurgical Probe product showed that the device performed equivalent or better and is therefore substantially equivalent in performance to the predicate devices.
Performance	The Stryker Stiletto Electrosurgical Probe allows for suction and irrigation of sterile irrigant solution and is intended to be used for electrosurgical cutting/coagulation during laparoscopic procedures. Electrical safety complies with IEC 60601.	SAME	SAME
Sterilization	Sterile/Single-Use and Non-Sterile/Reusable	Non-Sterile/Reusable	Non-Sterile/Reusable
Prescription Only	Yes	Yes	SAME
Biocompatibility	Unknown	Unknown	Conforms to ISO 10993

4. Device Description
   The GENICON Aquas Probes product line are multiple-use medical devices provided non-sterile. The probes are insulated for optional monopolar coagulation which enables a surgeon to manipulate, cut, or coagulate soft tissue or organs while performing laparoscopic procedures.

   The GENICON Aquas Probes have an outside diameter of 5 mm and are provided in varying lengths and tip configurations. Working lengths range from 20 cm up to 45 cm. Common tip configurations include L-Hook (Right Angle), J-Hook, Spatula, 45°, Knife, Ball, Needle, and Spoon Tips. Devices are provided with and without suction and irrigation element, which provides a working channel for suction and irrigation of sterile irrigant solution when attached to a compatible lavage device. Devices may also include retractable insulation, allowing the electrosurgical tip to be covered by additional insulation at the digression of the user.

   Device are intended to be reused up to 50 times, and may be sterilized by high-pressure steam autoclave.

5. Intended Use
   The GENICON Aquas Probes are instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

6. Technological Characteristics of the Subject Device Compared to the Predicate Device
   There are no new technologies being added to the device from the predicate in terms of finished device. The device has the same intended use and application as the predicate device.

7. Non-Clinical Tests

Non clinical tests were conducted to verify that the GENICON Reusable Electrosurgical Probe product line met all design specifications as the substantially equivalent predicate device and any additional test needed to show equivalence. Testing included in this submission include the following:

• Medical Electrical Equipment Testing	IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) IEC 60601-2-2:2009 IEC 60601-2-18:2009
• Autoclave Sterilization Validation	ISO 17655-1:2006 Cycle Count Testing

In addition the GENICON Aquas Probes product line has been compared to the predicate device through performance studies to test general use/performance and electrical safety and effectiveness.

Electrical performance of the device was completed following FDA guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" issued August 15, 2016. This requires testing on three different tissue types at minimum, default, and maximum generator power in order to simulate thermal spread across different tissue types. The spread is then measured under magnification, and recorded to be compared with the predicate product. Results showed an equivalent thermal spread under the same conditions across the different tissue types and power settings.

The GENICON Aquas Probes product line was also compared to the predicate device through bench testing which included visual & operational use, ergonomic forces, and electrical safety. Testing on performance and general ergonomic use showed that the devices met the same requirements as the predicate product.

8. Clinical Tests

There were no clinical trials performed on the GENICON Reusable Electrosurgical Probe product line.

9. Conclusions

The subject device has identical indications for use as the predicate device. The technological characteristics, non-clinical testing and performance and bench testing of the GENICON Aquas Probes product line show that the device is as safe, as effective, and meets the same performance standard. Therefore, the proposed GENICON Aquas Probes are substantially equivalent to the predicate.