October 17, 2017

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

Re: K171752
Trade/Device Name: X-Surge
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 2, 2017
Received: October 3, 2017

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. 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 contact the Division of Industry and Consumer Education (DICE) 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. 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 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 Industry and Consumer Education (DICE) 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,

Jennifer R. Stevenson -S3

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171752

Device Name
X-Surge

Indications for Use *(Describe)*
Endoscopic surgical procedures. It is a family of instruments which includes graspers, dissectors, and scissors, which are intended to be used to grasp, manipulate, cut, and cauterized soft tissue.

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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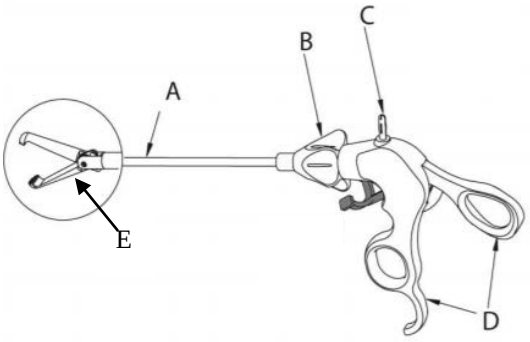
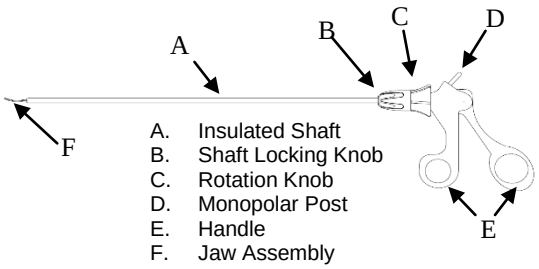
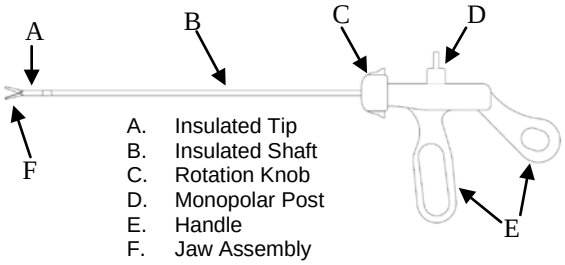
K171752
510(k) Summary

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
   July 7, 2017

2. Device Name
   - Trade Name – X-Surge
   - Common Name – Laparoscopic Instruments
   - Classification Name – Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400, Product Code GEI)

3. Substantially Equivalent Device
   Legally Marketed (unmodified device) GENICON Electrosurgical Instrumentation, K061417

Device	GENICON Electrosurgical Instrumentation 510(k) K061417	GENICON X-Surge 510(k): K171752
Intended Use	General & Plastic Surgery (GEI)	General & Plastic Surgery (GEI)
Component Design	**Current Electrosurgical Instrument Assembly**  A. Insulated Shaft B. Rotation Knob C. Monopolar Post D. Handle E. Jaw assembly	**Shaft and Handle assembly**  A. Insulated Shaft B. Shaft Locking Knob C. Rotation Knob D. Monopolar Post E. Handle F. Jaw Assembly **Tip and Handle assembly**  A. Insulated Tip B. Insulated Shaft C. Rotation Knob D. Monopolar Post E. Handle F. Jaw Assembly
Design	The GENICON disposable electrosurgical instruments are single use sterile instruments made from biocompatible plastic and stainless steel with a working length of 33cm. Current may be supplied by an approved electrosurgical generator which provides the ability for the coagulation of tissue when used with an appropriate ground electrode.	GENICON X-Surge instrumentation line is composed of single use sterile instruments (Reposable handle option available), made from biocompatible plastic, aluminum and stainless steel. When combined the working length is 20cm to 45cm. Current may be supplied by an approved electrosurgical generator which provides the ability for the coagulation of tissue when used with an appropriate ground electrode.

Diameter	3mm to 5mm	SAME
Materials	Patient Contact – AISI Stainless Steel, Radel Non-Patient Contact – Polycarbonate, Nylon, ABS, HDPE/LDPE	Patient Contact – AISI Stainless Steel, FEP Non-Patient Contact – Aluminum, Polycarbonate, Nylon, ABS, HDPE/LDPE, TPE
Testing	Fully assembled device was tested for cut and coagulation performance on three tissue samples of different origin. The test was performed at the lowest, default, and highest settings of a typical surgery center, and results were recorded.	Performance of the X-Surge product showed that the device performed equivalent or better and is therefore substantially equivalent in performance to the predicate device.
Performance	GENICON Disposable Electrosurgical Instrumentation is indicated for use in endoscopic surgical procedures. It is a family of instruments which includes graspers, dissectors, and scissors, which are intended to be used to grasp, manipulate, cut, and cauterize soft tissue.	SAME
Sterilization	Irradiation or Ethylene Oxide	SAME
Prescription Only	YES	SAME
Biocompatibility	Conforms to ISO10993	SAME

4. Device Description

   The GENICON X-Surge monopolar laparoscopic instruments are sterile packaged Single Use Mono-Polar attachments intended for use in combination with a compatible reposable handle. It is designed to include graspers, dissectors, and scissors, intended to grasp, manipulate, cut, and cauterize soft tissue. The device diameter has a range of 3 - 5mm, and connects to a handle with the appropriate configuration. The handle has a male cautery connector that will be utilized for cauterizing soft tissue when attached to standard monopolar cautery cables and their generators.

   The disposable shaft and tips are composed of an aluminum outer shaft, and a stainless steel drive rod which connects to the scissor blades and interacts with the handle activation rod. The outer insulation consists of fluorinated ethylene polypropylene which is an insulation with functional material properties that are improved over Polytetrafluoroethylene PTFE, and is less rigid than Radel insulation. The disposable shafts and tips are to be supplied sterile in single unit trays with Tyvek lid, similar to the current GENICON electrosurgical instrumentation line. The Reposable handle is sterilized by the user using an autoclave process and is then connected to the sterile disposable shaft or tip. Once the procedure is completed, the instrument ends are disassembled from the handle, and are disposed of appropriately, and the handle is cleaned and sterilized for the next procedure.

5. Intended Use

   The GENICON X-Surge instrumentation line is intended for use in endoscopic surgical procedures. It is a family of instruments which includes graspers, dissectors, and scissors, which are intended to be used to grasp, manipulate, cut, and cauterize soft tissue.

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. The X-Surge device will have an additional connection point. The X-Surge device will also have a detachable shaft/tip from the handle, but the same technology is used when discussing function of the device. In both instances electrical current will be passed through an insulated shaft and applied to the appropriate tip assembly to grasp, manipulate, cut, and cauterize soft tissues.

7. Non-Clinical Tests
   Non clinical tests were conducted to verify that the X-Surge 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:
   - Biocompatibility Testing
     - Cytotoxicity Test – ISO 10993-5:2009
     - Skin Sensitization/Irritation Test – ISO 10993-10:2010
     - Acute System Toxicity Test - ISO 10993-11:2010
   - Medical Electrical Equipment testing
     - For both single use and reusable IEC 60601-1, IEC 60601-2
   - Aging Study under ETO
   - Aging Study under Gamma
   - Autoclave testing verification

   In addition the GENICON X-Surge instrumentation line has been compared to the predicate device through performance studies to test cutting performance and electrical safety and effectiveness.

   Cut performance across different mediums using the predicate as a baseline was completed in order to compare any instances of slipping, overall cut length across testing mediums, and scissor geometry including: scissor length, scissor width, and opening and closing dimensions. Testing showed the X-Surge device performed equivalent or better than the predicate Genicon product.

   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 or less area of thermal spread under the same conditions across the different tissue types and power settings.

   The GENICON X-Surge instrumentation line was also compared to the predicate device through bench testing which included visual & operational use, ergonomic forces (i.e. attachment, activation, etc.). Testing on performance and general ergonomic use showed that the X-Surge device met the same requirements as the predicate product in terms of closure force, opening angle, finger spacing, and rotation knob interaction.

8. Clinical Tests
   There were no clinical trials performed on the GENICON X-Surge instrumentation 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 X-Surge instrumentation line show that the device is as safe, as effective, and meets the same performance standard. Therefore, the proposed GENICON X-Surge instrumentation is substantially equivalent to the predicate.