DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 2, 2017

JACO , LLC dba Macan Manufacturing and BNA Burz North America
% Bill Mclain
President and Principal Consultant
Keystone Regulatory Services, LLC
342 East Main Street, Suite 207
Leola, Pennsylvania 17540

Re: K170054
Trade/Device Name: iSurg (MC6B)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 5, 2017
Received: January 6, 2017

Dear Bill McLain:

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 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170054

Device Name
ESU (Electrosurgical Unit) Generator Model MC6B/iSurg

Indications for Use *(Describe)*

Cutting and coagulation of skin.

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.

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Section 5

510(k) Summary - K170054

5.1 Submission Correspondent and Owner

Sponsors (Co-Owners)

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5.2 Date Summary Prepared

September 27, 2017

5.3 Device Trade Name

iSurg(MC6B)

5.4 Device Common Name

Electrosurgical Generator and Electrodes.

5.5 Device Classification Name

Electrosurgical, Cutting and Coagulation and Accessories. Product code GEI. Classified at 21 CFR Part 878.4400.

5.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

The iSurg(MC6B) is substantially equivalent to the Surgi-Max Ultra cleared under K170107and the JACO, LLC dba Macan Manufacturing RadioSurge^{TM} Model MC6A cleared under K050735.

5.7 Description Of The Device

The iSurg(MC6B) is an isolated output monopolar electrosurgical generator configured as a table top standalone device, Height 3.5in (89mm), Width 10.5in (267mm), Depth 6.5in (165mm), Weight 6lb (2,73kg) It produces 50 watts into 500 ohms at 3.0 MHz.

The iSurg(MC6B) generates RF current via an AM modulated power oscillator comprised of a class C beam power vacuum tube Hartley oscillator. The power oscillator runs at full power when actuated. Power control is by means of an attenuator in the form of variable air capacitor.

MOPP (Means of Patient Protection) is in the form of magnetic coupling to an isolated winding on a separate core in the RF coil providing type BF floating patient applied parts in accordance with IEC 60601-2-2. The RF coil primary serves as an intermediate stage with PE connection. MOOP is provided by the low voltage control board (61.010) which galvanically isolates the foot pedal from mains and earth and couples to the oscillator through opto-coupler and relay. SELV common on this board floats. The 81.001A Switch Board uses high isolation relays powered by the low voltage board to isolate the relay coils from the oscillator board. Oscillator actuation is by means of earthing the cathode of the beam power tube via a relay; oscillator OFF state is when the cathode of the beam power tube floats. Tube bias is by means of grid leak via the 10K grid load. The 10K grid load resistor is wire wound type with significant inductance: the current to ground through it is close to DC accordingly. It is current through this resistor that is sensed for the RF ON indicator and active tone (a function of the low voltage control board). The low voltage board also includes a warm up delay to prevent cathode stripping of the vacuum tube.

5.8 Intended Use

The indication for use statement is as follows:

Cutting and coagulation of skin.

5.9 Technological Characteristics

The iSurg(MC6B) has identical characteristics in relation to the predicate Surgi-Max Ultra and reference JACO, LLC dba Macan Manufacturing RadioSurge^{TM} Model MC6A when considered together. The characteristics are identical in relation to:

- Indication for Use,
- Specifications,
- Operating Modes,
- Nominal Power
- Cut, Blend, and Coag Output Energies,
- Output Voltages,
- Source Impedance,
- Operating Frequency,
- Power Control, and
- Operational Duty Cycle.

5.10 Summary of Substantial Equivalence

The following table summarizes the basis for substantial equivalence.

Table 5.1: Substantial Equivalence Table

Features	**iSurg(MC6B)(Proposed Device)**	**Surgi-Max Ultra (K170107) (Predicate)**	**JACO, LLC dba Macan Manufacturing RadioSurge™ Model MC6A (K050735) (Predicate)**
Indications	Cutting and coagulating skin	Cutting, coagulation, hemostasis, skin surgery (Paraphrased)	Dental applications (Paraphrased)
Prescription or OTC Use	Prescription	Prescription	Prescription
FDA Code	GEI Electrosurgical	GEI Electrosurgical	EKZ Dental
Specifications	Monopolar, Type BF	Monopolar and Bi-Polar, Type BF	Monopolar, Type BF
Operating Mode	Cut, Cut/Coag, Coag	Cut, Blend, Hemo, Bipolar, Bipolar Turbo	Cut, Cut/Coag, Coag
Nominal Power	50W Nominal	170W Nominal	50W Nominal
Cut Output Energy	50W Nominal into 500 ohms	Not stated in the 510(k) Summary	50W Nominal into 100 ohms
Blend Output Energy	50W Nominal into 500 ohms	Not stated in the 510(k) Summary	50W Nominal into 100 ohms
Coag Output Energy	25W Nominal into 500 ohms	Not Stated in the 510(k) Summary	25W Nominal into 100 ohms
Output Voltage	520V pk	1200V pk	520V pk
Source Impedance	500 ohms	Not stated in the 510(k) Summary	500 ohms
Operating Frequency	3.0 MHz	4.0 MHz in Monopolar Mode	3.0 MHz
Power Control	Analong, continously variable	Not stated in 510(k) Summary	Analong, continously variable
Operational Duty Cycle	10 seconds ON, 20 seconds OFF	10 seconds ON, 30 seconds OFF	10 seconds ON, 20 seconds OFF

Table 5.1: (continued)

Features	**Proposed Device**	**Predicate Device**	**Reference Device**
Software	None	Contains Software	None
Accessories	As cleared in K052622. Handpiece, Dispersive Pad, Dispersive Cord, Foot Switch, Electrodes(RF1, RF11, RL33, RL34, RC51, RC52)	Unknown	As cleared in K052622. Handpiece, Dispersive Pad, Dispersive Cord, Foot Switch, Electrodes(RF1, RF11, RL33, RL34, RC51, RC52)

5.11 Non-Clinical Testing

JACO, LLC dba Macan Manufacturing and BNA Burz North America, Inc. have declared conformity to the following relevant consensus standards:

- AAMI ANSI 60601-1 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories [Including: Technical Corrigendum 1 (2014)] 1/27/2015

Histology Study
A histological evaluation of the cutting modes on porcine skin was conducted. The purpose of this study was to assess the length and depth of electrocautery effect (with these two dimensions defining the area of effect) on ex-vivo pig skin using histologic evaluation. Three different electrodes were used representing worst-case scenarios.

Five different electrocautery test article effects (comprising combinations of the specified electrodes with different waveforms designated as Groups 1-5) were each evaluated at minimal, nominal, and maximal power in triplicate. No cautery effect was appreciable within any group at minimal power. However, in all nominal and maximal power samples, distinct regions of cautery effect were evident within the dermis.

The incision electrode employing cut and blend waveforms had V shaped incisions that extended into the mid-dermis accompanied by small halos of cautery effect. Nominal and maximal power levels had similarly-sized areas of cautery effect for both waveforms.

The excision electrode employing cut and blend waveforms provided broad, shallow excisions with a curvilinear appearance and slightly raised margins extending into the superficial dermis accompanied by a thin halo of cautery effect. A direct relationship was observed with increased area of cautery effect occurring with increasing power levels.

The ball electrode employing a hard coagulation waveform affected a small focal area (approximately 2x1 mm), had a slightly convex central area on histology, and was accompanied by a small, focal halo of cautery effect within the superficial dermis. The relationship of cautery area to waveform power is somewhat uncertain; although average area of effect was slightly greater for nominal vs. maximal power, the small dimensions of test article effect could have lead to slight underestimation of maximal power effect due to sectioning variation.

At minimal power, no cautery effect was evident for any treatment group. For Group 1, with the incision electrode utilizing cut mode, the largest width of cautery effect was observed with maximal power as 0.421 mm (width); nominal power had slightly greater depth at 0.210 mm but was similar to maximal power (0.125 mm depth). For Group 2, with the incisoin electrode utilizing blend mode the largest area of cautery effect was observed with nominal power and was 0.473mm (width) and 0.190 mm (depth); but was similar to maximal values (0.369 mm for depth) and (0.148mm for width). For Group 3, with the excision electrode utilizing cut mode the largest area of cautery effect was observed with maximal power and was 6.239 mm (width) and 1.612 mm (depth). For Group 4, with the excision electrode utilizing cut mode the largest area of cautery effect was observed with

maximal power was 6.039 mm (width) and 0.917 mm (depth). For Group 5, with the ball electrode utilizing the hard coagulation mode the largest area of cautery effect was observed with with nominal power and was 2.256 mm (width) and 1.209 mm (depth), although small size of test article effect could have slightly underestimated cautery effect within the maximal cohort for this electrode and waveform combination.

5.12 Biocompatibilty

Biocompatibility testing was not submitted in association with this 510(k). Rather, patient contacting materials associated with electrodes were referenced in relation to the reference device JACO, LLC dba Macan Manufacturing RadioSurge^{TM} Model MC6A cleared under K050735.

5.13 Clinical Testing

No clinical testing was performed in association with this submission.

5.14 Conclusions

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate device.