DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 2, 2017

KARL STORZ Endoscopy-America, Inc.
% Dawn Tibodeau
Third Party 510(k) Project Coordinator
TŰV SŰD America Inc.
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

Re: K171717
Trade/Device Name: Autocon III 400
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 26, 2017
Received: July 31, 2017

Dear Dawn Tibodeau:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Not yet assigned K171717

Device Name
AUTOCON III 400

Indications for Use *(Describe)*
The AUTOCON III 400 is intended for use by qualified surgeons to provide a high frequency electrical current for monopolar and bipolar cutting and coagulation of tissue structures during surgical operations.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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KARL STORZ—ENDOSKOPE

7. 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	AnnaLisa Smullin Regulatory Engineer Phone: (424) 218-8376 Fax: (424) 218-8519
Date of Preparation:	March 5, 2017
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: AUTOCON III 400 Classification Name: Electrosurgical Generator
Regulatory Class:	II
Product Code:	GEI
Regulation:	21 CFR part 878.4400 (Electrosurgical cutting and coagulation device and accessories)
Predicate Device(s):	Primary Predicate Device: AUTOCON II 400 (K062464) Second Predicate Device: ERBE VIO 300D (K060484) These predicate devices have not been subject to a design-related recall.
Device Description:	The AUTOCON III 400 is an electrosurgical unit (ESU) that generates High Frequency (HF) electrical current to cut and/or coagulate tissue. AUTOCON III 400 offers a total of 37 different modes that can be divided into 4 main categories: Monopolar cutting (13 modes), monopolar coagulation (11 modes), bipolar cutting (4 modes), and bipolar coagulation (9 modes). The various modes in each category represent different settings that provide controlled cutting and coagulation. Each mode can be defined by the waveform type, power, crest factor, and duty cycle which correspond to different tissue effects.

	AUTOCON III 400 consists of a generator, a foot switch, and a power cord. A touchscreen user interface displays the connection status of accessories and peripherals and allows the user to select modes, power settings, effect, and various other settings. AUTOCON III 400 has a bipolar socket, a monopolar socket, and neutral electrode socket for the instruments and accessories with which the generator is compatible. Contact quality indicators are displayed to indicate if the neutral electrodes are correctly connected or not.
Intended Use:	The AUTOCON III 400 is intended for use by qualified surgeons to provide a high frequency electrical current for monopolar and bipolar cutting and coagulation.
Indications For Use:	The AUTOCON III 400 is intended for use by qualified surgeons to provide a high frequency electrical current for monopolar and bipolar cutting and coagulation of tissue structures during surgical operations.
Technological Characteristics:	The subject and predicate devices are electrosurgical generators used to cut and coagulate tissue. The technological differences between the systems are described in the table below.

	AUTOCON III 400 (Proposed)	**AUTOCON II 400** (K062464)	**ERBE VIO 300D** (K060484)
Manufacturer	KARL STORZ Endoscopy	KARL STORZ Endoscopy	ERBE USA, Inc.
Product Code	GEI	GEI	GEI
Energy	Monopolar, Bipolar	Monopolar, Bipolar	Monopolar, Bipolar
Neutral Electrode	Compatible FDA cleared Single or Split Electrodes	Compatible FDA cleared Single or Split Electrodes	Compatible FDA cleared Single or Split Electrodes
Electrode Monitoring System	Yes	Yes	Yes
System Voltage	100-127 V	100-127 V	100-120 V
Connection to KARL STORZ OR1™	Yes	Yes	No
Monopolar Cut Modes			
# of Modes	13	6	7
Max Power	400W (at 200Ω)	300W (at 500Ω)	300W (at 500Ω)
Output Frequency	350kHz	350kHz	350kHz
Max Voltage Output	1600Vp	1450Vp	1550Vp
Crest Factor	1.5, 3.5	1.4-3.8	1.4
Wave Forms	-Sinusoidal Constant -Sinusoidal Modulated -Sinusoidal Alternating	-Sinusoidal Constant -Sinusoidal Modulated -Sinusoidal Alternating	-Sinusoidal Constant -Sinusoidal Modulated -Sinusoidal Alternating

		Cut/Coag/Pause Phases	Cut/Coag/Pause Phases	Cut/Coag/Pause Phases
	Monopolar Coagulation Modes			
	# of Modes	11	3	8
	Max Power	250W (at 500Ω)	200W (at 500Ω)	200W (at 500Ω)
	Output Frequency	350kHz	350kHz	350kHz
	Max Voltage Output	5000Vp	4300Vp	4300Vp
	Crest Factor	1.6-7.4	1.4-7.4	3.7-5.3
	Wave Forms	-Sinusoidal Constant -Sinusoidal Modulated -Pulse Modulated	-Sinusoidal Constant -Sinusoidal Modulated -Pulse Modulated	-Sinusoidal Constant -Sinusoidal Modulated -Pulse Modulated
	Bipolar Cut Modes			
	# of Modes	4	4	3
	Max Power	400W (at 75Ω)	370W (at 500Ω)	370W (at 500Ω)
	Output Frequency	350kHz	350kHz	350kHz
	Max Voltage Output	500Vp	740Vp	770Vp
	Crest Factor	1.5-1.6	1.4	1.4
	Wave Forms	-Sinusoidal Constant	-Sinusoidal Constant	-Sinusoidal Constant
	Bipolar Coagulation Modes			
	# of Modes	9	5	5
	Max Power	350W (at 25Ω)	200W (at 50Ω)	200W (at 50Ω)
	Output Frequency	350kHz	350kHz	350kHz
	Max Voltage Output	550Vp	190Vp	560Vp
	Crest Factor	1.5-3.8	1.4	1.4-3.8
	Wave Forms	-Sinusoidal Constant -Pulse Modulated	-Sinusoidal Constant -Pulse Modulated	-Sinusoidal Constant -Pulse Modulated

Non-Clinical Performance Data:

<u>Electrical Safety and Electromagnetic Compatibility (EMC) Summary</u>

The electrical safety and EMC data submitted for AUTOCON III 400 is in compliance with the following FDA recognized standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-2

<u>Performance Testing – Bench Top Summary</u>

Comparative verification testing has been performed per FDA Guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued on August 15, 2016 for each major component and for the system.

- Electrosurgical Unit (ESU)
  - Technical Specifications

	○ Output Waveform at the rated load ○ Power Output at maximum and half-of-maximum intensity over the range of expected loads • Miscellaneous Components/Accessories ○ Functional testing of accessories • System Testing ○ Thermal Effects on Tissue (liver, kidney, muscle) ○ Contact Quality Monitoring (CQM) Testing confirmed that comparable tissue effects and electrical waveforms could be achieved for all modes of operation.
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was deemed sufficient to assess safety and effectiveness and establish substantial equivalence.
Conclusion:	The conclusions drawn from the non-clinical tests such as the bench top performance data, the software data, the electrical safety data, and the electromagnetic compatibility data demonstrated that the subject device is as safe as and as effective as the predicate devices. As such, we concluded that the substantial equivalence of the subject and the predicate devices has been met and the differences between the subject and the predicate devices do not raise new questions of safety and effectiveness.