October 28, 2019

HS Hospital Service SPA
% Silvia Scarpellini
Regulatory Affairs Consultant
ISEMED srl
Via P. Togliatti 19/X
Imola, 40026 Italy

Re: K182605
Trade/Device Name: HS AMICA devices family
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 17, 2018
Received: September 21, 2018

Dear Silvia Scarpellini:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K182605

Device Name
HS AMICA DEVICES FAMILY

Indications for Use *(Describe)*
Coagulation (thermo-ablation) of soft tissue. Not for use in cardiac 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.

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510(K) SUMMARY

HS AMICA devices family

This 510(k) Summary is being submitted in accordance with the requirements of 21CFR 807.92.

1. General Information

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Summary Preparation Date: October 24, 2019

2. Device

Device Name	HS AMICA devices family
Classification name	Electrosurgical cutting and coagulation device and accessories
Product Code	GEI
Regulation number	878.4400
Class	II

3. Predicate Device

HS AMICA devices family is substantially equivalent to the following device legally marketed in US:

Applicant	*Device name*	*510(k) Number*
H.S. HOSPITAL SERVICE S.P.A.	HS AMICA devices family	K150112

4. Device Description

HS AMICA devices family is the advance version of the design of the legally marketed HS AMICA devices family Ablation System (K150112).
AMICA-GEN is available in the following different models (same as in K150112):

- AMICA-GEN AGN: Microwave generator only
- AMICA-GEN AGN-R: Radiofrequency generator only
- AMICA-GEN AGN-H: Hybrid Microwave and Radiofrequency generator (NB: the MW and RF outputs can never be activated simultaneously. The actual energy source in use depends on the applied part type, RF or MW, connected to the generator)

HS AMICA devices family is a fully featured soft tissue ablation system that is intended for coagulation (thermo-ablation) of soft tissues. Not for use in cardiac procedures.

There are several available variants of PROBE (i.e. the applied parts for direct energy delivery into the patient's body for percutaneous or intra-operative use):

- AMICA-PROBE's design is identical to that already cleared in K150112: disposable device for MW energy delivery into tissues through an embedded coaxial antenna of asymmetric dipole type. The antenna is lodged into a stainless steel needle serving as introducer. AMICA-PROBE is internally cooled all along the introducer length. The distal emitting tip (uncooled) –terminated by a sharp pyramidal metallic tip for facilitating tissue penetration- is endowed with a patented miniaturized choke for reflected waves confinement, so as to ensure a more spherical ablation shape;
- RF AMICA-PROBE 's design is identical to that already cleared in K150112.
  RF AMICA-PROBE is a monopolar (i.e. single terminal), straight, stainless steel electrode, covered with an insulating sheath throughout its length, but for a few millimeters or centimeters at its distal tip (therefore referred to as "exposed tip"), which is terminated by a sharp pyramidal point for facilitating tissue penetration. RF AMICA-PROBE is internally cooled down to the exposed tip. When using RF AMICA-PROBE the current output to the patient's body delivered through the probe exposed tip must return to the generator through one or more "return

electrodes" (also referred to as "grounding pads" or "dispersion plates" or "neutral electrodes"), in the form of metallic foils attached to the patient's skin and directly connected to the current generator.

HS AMICA devices family consists of non-sterile reusable electronic parts, and sterile disposable applied parts, identically to the predicate device HS AMICA devices family (K150112). The sterilization method used for all the sterile components is Ethylene Oxide. The method is exactly the same used and validated for the predicate device cleared in HS AMICA devices family.

The microwave devices can be operated in continuous and PULSE mode. The PULSE mode is new operational mode with a duty cycle of 40% and a max output power of 190 Watts.

5. Indications for use

Coagulation (thermo-ablation) of soft tissues. Not for use in cardiac procedures.

6. Comparison of technological characteristics with the predicate devices

This subject device is the advance version of the previous HS AMICA devices family (K150112), that has been included in the present submission as predicate device. They have identical indications for use and same technology features, with the following different technical features in the subject device:

a) new option of Microwave power delivery algorithms; namely, the "PULSED" mode, which provides for intermittent energy delivery according to a given working cycle.
b) software version updated to Rev. 1.7.1

The comparison of the subject and predicate devices based on indications for use, technology and performance characteristics, is summarized in the following table and discussed below.

510(k) Summary for K182605

H.S. Hospital Service S.p.A. **HS AMICA devices family**

				PREDICATE DEVICE
	H.S. HOSPITAL SERVICE			**H.S. HOSPITAL SERVICE**
	HS AMICA DEVICES FAMILY			**AMICA GEN AGN-H**
	AMICA GEN AGN	**AMICA GEN AGN-H**	**AMICA GEN AGN-R**	
510(k) Number				K150112
General features				
Classification	II			II
Regulation number	878.4400			878.4400
Product Code	GEI			GEI
Indication statements				
Intended use		Coagulation (thermo-ablation) of soft tissues. Not for use in cardiac procedures		Coagulation (thermo-ablation) of soft tissues. Not for use in cardiac procedures
Mechanism of action	Interstitial thermoablation of soft tissues through controlled emission of MW energy at the tip of a microwave coaxial antenna lodged into a needle	Interstitial thermoablation of soft tissues through controlled emission of MW energy or RF energy (non-simultaneous), respectively at the tip of a microwave coaxial	Interstitial thermoablation of soft tissues through controlled emission of RF energy at the tip of RF electrodes	Interstitial thermoablation of soft tissues through controlled emission of MW energy or RF energy (non-simultaneous), respectively at the tip of a microwave coaxial

				PREDICATE DEVICE
	H.S. HOSPITAL SERVICE			**H.S. HOSPITAL SERVICE**
	HS AMICA DEVICES FAMILY			**AMICA GEN AGN-H**
	AMICA GEN AGN	**AMICA GEN AGN-H**	**AMICA GEN AGN-R**	
		antenna lodged into a needle or at the tip of RF electrodes		antenna lodged into a needle or at the tip of RF electrodes
Technical features				
Design structure	• Generator • Applicator (coaxial microwave applicator) • Cooling system (peristaltic pump, coolant tank and tubing for applicator cooling) • Footswitch	• Generator • Applicators (coaxial microwave applicator, RF applicator) • Return pad • Cooling system (peristaltic pump, coolant tank and tubing for applicator cooling) • Footswitch	• Generator • Applicator (RF applicator) • Return pad • Cooling system (peristaltic pump, coolant tank and tubing for applicator cooling) • Footswitch	• Generator • Applicators (coaxial microwave applicator, RF applicator) • Return pad • Cooling system (peristaltic pump, coolant tank and tubing for applicator cooling) • Footswitch
Microwave applicator Connection	Yes	Yes	No	Yes
Radiofrequency applicator connection	No	Yes	Yes	Yes
Return pad connection	No	Yes	Yes	Yes

				PREDICATE DEVICE
	H.S. HOSPITAL SERVICE			**H.S. HOSPITAL SERVICE**
	HS AMICA DEVICES FAMILY			**AMICA GEN AGN-H**
	AMICA GEN AGN	**AMICA GEN AGN-H**	**AMICA GEN AGN-R**	
Cooling system management	Automatic	Automatic	Automatic	Automatic
Coolant	Sterile Disposable saline solution	Sterile Disposable saline solution	Sterile Disposable saline solution	Sterile Disposable saline solution
Needle temperature range (°C)	From 16 to 100	From 16 to 100	From 16 to 100	From 16 to 100
Treatment time range (min)	Up to 30	Up to 30	Up to 30	Up to 30
Microwave emission features				
Microwave frequency (MHz)	2450	2450	-	2450
Output power (W)	Up to 140 (for continuous mode) Up to 190 (for pulsed mode)	Up to 140 (for continuous mode) Up to 190 (for pulsed mode)	-	Up to 140 (only continuous mode available)
Microwave power delivered control	Manual	Manual	-	Manual
Microwave applicators features				
Microwave applicator	11-14-16	11-14-16	-	11-14-16

				PREDICATE DEVICE
	H.S. HOSPITAL SERVICE			**H.S. HOSPITAL SERVICE**
	HS AMICA DEVICES FAMILY			**AMICA GEN AGN-H**
	AMICA GEN AGN	**AMICA GEN AGN-H**	**AMICA GEN AGN-R**	
needle diameters (Gauge)				
Microwave applicator needle lengths (cm)	15-20-27	15-20-27	-	15-20-27
Microwave applicator terminal lengths (mm)	19	19	-	19
Radiofrequency emission features				
Radiofrequency frequency (kHz)	-	450	450	450
Radiofrequency power (W)	-	Up to 200	Up to 200	Up to 200
Radiofrequency power delivery control	-	Manual or Automatic	Manual or Automatic	Manual or Automatic
Radiofrequency power output mode	-	Monopolar	Monopolar	Monopolar
Operative impedance range (Ω)	-	From 25 to 1000	From 25 to 1000	From 25 to 1000
Radiofrequency applicators features without local fluid delivery				
Radiofrequency	-	Single - Cluster	Single - Cluster	Single - Cluster

				PREDICATE DEVICE
	H.S. HOSPITAL SERVICE			**H.S. HOSPITAL SERVICE**
	HS AMICA DEVICES FAMILY			**AMICA GEN AGN-H**
	AMICA GEN AGN	**AMICA GEN AGN-H**	**AMICA GEN AGN-R**	
applicator typologies				
Radiofrequency applicator needle Diameters (Gauge)	-	17-18	17-18	17-18
Radiofrequency applicator needle lengths (cm)	-	7-10-15-20-25-27	7-10-15-20-25-27	7-10-15-20-25-27
Radiofrequency electrode lengths (mm)	-	5-7-10-15-20-25-30-35	5-7-10-15-20-25-30-35	5-7-10-15-20-25-30-35
Radiofrequency applicators features with local fluid delivery				
Radiofrequency applicator typologies	-	Single	Single	-
Radiofrequency applicator needle Diameters (Gauge)	-	17-18	17-18	-
Radiofrequency applicator needle lengths (Cm)	-	7-10-15-20-25-27	7-10-15-20-25-27	-
Radiofrequency active	-	5-7-10-15-20-25-30-35	5-7-10-15-20-25-30-35	-

				PREDICATE DEVICE
	H.S. HOSPITAL SERVICE			**H.S. HOSPITAL SERVICE**
	HS AMICA DEVICES FAMILY			**AMICA GEN AGN-H**
	AMICA GEN AGN	**AMICA GEN AGN-H**	**AMICA GEN AGN-R**	
tip lengths (mm)				
Dispensing holes in probe variants featuring local fluid delivery	-	1 or 2	1 or 2	-
Local fluid delivery (Yes/No)	-	Yes	Yes	No
Safety features				
Condition of use of applicators	Sterile - disposable	Sterile - disposable	Sterile - disposable	Sterile - disposable

The list of the differences:

a) New option of Microwave power delivery algorithms; namely, the "PULSED" mode, which provides for intermittent energy delivery according to a given working cycle

The difference does not raise new effectiveness or safety issues for the following reasons:

- HS AMICA devices family does not establish the power delivery mode to be used. This is set by physician.
- The total maximum output power of the PULSE mode within the ablation period is 190x40%=76W, which is less than the maximum output power 140W of the continuous mode in the predicate device.
- Thermal Effects tests with ex-vivo bovine liver, kidney and muscle demonstrated the ablation can be done with the PULSE mode as safely and effectively as the continuous mode.

b) Software version updated to Rev. 1.7.1

HS AMICA medical devices family has been developed and validated according to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices requirements FDA–May 2005 and IEC 62304.

In conclusion, the different technological features of HS AMICA devices family will not affect its classification, working principle, intended use, indications for use and target population and will not rise up new safety and effectiveness questions making HS AMICA devices family equivalent to predicate device (K150112).

7. Performance Data

The HS AMICA medical devices family and accessories and the predicate device are substantially equivalent in design concepts, technologies and materials. HS AMICA medical devices family has been verified through rigorous testing that, in part, supports the compliance of Ablation System and Accessories to the standards listed below. The system passed all pre-determined acceptance criteria identified in the test plan.

HS AMICA devices family complies with:

- EN 60601-1:2006+A11:2011+A1:2013
- EN 60601-2-2:2009+A11:2011
- EN60601-2-6:2015+A11:2016
- EN 60601-1-2:2015
- IEC 62304:2015-06

- ISO 10993-1:2009
- ISO 10993-7-2008
- ISO 11135-2014
- ISO 11138-1-2006
- ISO 11737-1-2006
- ISO 11737-2-2009

- Performance test-bench

Thermal Effects performance tests, as suggested in FDA guidance Premarket Notification (510(K)) Submissions for Electrosurgical Devices for General Surgery, were conducted with the proposed device. Testing results with Ex-Vivo bovine liver, kidney and muscle demonstrated that HS AMICA devices family can perform as safely and effectively as the predicate device K150112 in coagulation of soft tissues with microwave energy. Results indicated that PULSE mode ablations allowed for slightly more spherical ablations, and thus offers physicians a wider range of options for tailoring the ablation shape and size to each individual clinical case.

8. Conclusions

Based on the results of Verification and Validation Studies, H.S. Hospital Service S.p.A. concludes that the advance devices HS AMICA devices family are as safe and effective as the predicate device (K150112).