February 9, 2024

HS Hospital Service SPA
% Guido Bonapace
Consultant
Isemed s.r.l
Via Palmiro Togliatti 19/X
Imola, Bologna 40026
Italy

Re: K232072
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: December 13, 2023
Received: December 13, 2023

Dear Guido Bonapace:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.02.09 13:55:28 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232072

Device Name
HS AMICA devices family

Indications for Use *(Describe)*
Coagulation (thermoablation) 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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1. General Information

Submitter: HS Hospital Service establishment is at:
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Establishment Registration Number: 8010312

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Summary Prepared Date: *February 09, 2024*

2. Device

Name of Device: HS AMICA devices family
(AMICA-GEN AGN-H-1.3 and AGN-3.3, AMICA-PROBE 17G & 18G applicators)
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Regulation Class: II
Product Code: GEI

3. Predicate Devices

The AMICA-GEN models AGN-H-1.3 and AGN-3.3 and AMICA-PROBE 17G & 18G applicators are claimed substantially equivalent to the following devices legally marketed in the US:

Applicant	Device name	510(k) Number
H.S. Hospital Service S.p.A.	HS AMICA devices family	K182605

These predicate devices have not been subject to a design-related recall.

4. Device Description

The devices subject of this submission, generator AGN-H-1.3, generator AGN-3.3 and AMICA-PROBE 17G & 18G applicators, belong to the HS AMICA devices family and they represent an evolution and implementation of previous models, already authorized by FDA under K182605. The working configuration of the HS AMICA commercial system consists of:

- A programmable generator for the generation and control of the energy required for the thermoablative treatment;
- Disposable applied parts (or applicators) for the direct release of energy into the patients or for temperature measurements inside the patient's body.

The result is an integrated system for thermoablation of tissues through controlled emission of non-ionizing electromagnetic radiations in the microwave and radiofrequency ranges. The generators and its accessories are able to emit only microwaves (MW, 2450 MHz), or only radiofrequency waves (RF, 450 kHz) or either microwaves or radiofrequency waves (not simultaneously). The new electrosurgical devices introduced by H.S. Hospital Service S.p.A. are the AMICA-GEN models named AGN-H-1.3 and AGN-3.3, along with 17G and 18G AMICA-PROBE disposable applicators.

AGN-H-1.3 and AGN-3.3, are identical to the approved AMICA-GEN models named AGN-H-1.2 and AGN-3.2, respectively, as for principles of operation, design, architecture, and critical components; however, the new models feature a higher MW rated power, increased from 190W to 250W. This power increase solely affects the PULSED energy delivery mode and does not alter the total amount of microwave energy that the HS AMICA system may administer to a patient in a single treatment session. To support the increased MW power rating, new generator models use AC-DC power supply units with 600W DC output, whereas previously approved models used 500W AC-DC power supply units.

Both new AMICA-GEN models and previously approved models feature a monochromatic touchscreen LCD display (serving as human-machine interface), a rotary knob for parameters selection, a set of connection ports, buttons and indicators, and a built-in peristaltic pump for inner convective cooling of the applied parts used in conjunction with the generator: none of these features is changed in new models with respect to previously approved models.

The new variants of AMICA-PROBE disposable applicators are characterized by a smaller diameter of the needle and shaft length options limited to 70mm, 100mm or 150mm; these applicators better serve the purpose of further minimizing treatment invasiveness and further enhancing safety in clinical applications that prioritize the tailoring of the treatment area to the target tissues geometry rather than the absolute maximization of the ablation volume. The new models of AMICA-PROBE share the same performance specifications and the same manufacturing materials with already approved applicators (K182605). The difference with previous models resides in the probe gauge (i.e., the outer diameter of the introducing cannula), which is 17G and 18G in the new models vs 11G, 14G or 16G in the previously approved devices.
As predicate devices, the new applicators are supplied in sterile conditions and cannot be re-sterilized; the sterile kits composed by the microwave applicators and their disposable accessories (a scalpel for skin pre-incision, and a self-adhesive drape for better delimitation of the operating area) are the same as for predicate devices. The sterilization method used for the sterile kits is Ethylene Oxide (unchanged with respect to what was described and validated in K182605).

5. Indications for Use

Coagulation (thermoablation) of soft tissue.
Not for use in cardiac procedures.

6. Substantial equivalence comparison

In the table below a detailed comparison between subject devices (AMICA-GEN AGN-H-1.3, AGN-3.3 and AMICA PROBE applicators) and predicate devices HS AMICA devices family (K182605) is provided.

Characteristic	Proposed Device	Main Predicate
	AMICA-GEN AGN-H-1.3 **AMICA-GEN AGN-3.3**	**HS AMICA devices family** **(AGN-H-1.2 and AGN-3.2)** **K182605**
Manufacturer	**H.S. Hospital Service S.p.A.**	**H.S. Hospital Service S.p.A.**
Classification Name	Electrosurgical cutting and coagulation device and accessories.	Electrosurgical cutting and coagulation device and accessories.
Regulation number	878.4400	878.4400
Regulatory class	II	II
Classification Product Code	GEI	GEI
Indications for use	Coagulation (thermoablation) of soft tissue. Not for use in cardiac procedures.	Coagulation (thermoablation) of soft tissue. Not for use in cardiac procedures.
Prescription or OTC	Prescription use.	Prescription use.
Mechanism of action	Thermoablation of soft tissues through controlled emission of MW energy or RF energy (nonsimultaneous), respectively at the tip of a microwave coaxial antenna lodged into a needle or at the tip of RF electrodes.	Thermoablation of soft tissues through controlled emission of MW energy or RF energy (nonsimultaneous), respectively at the tip of a microwave coaxial antenna lodged into a needle or at the tip of RF electrodes.
Classification	Risk class (93/42/CE as modified by 2007/47/EEC): IIb Electrical class (EN60601-1): I BF EMC Class (EN60601-1-2): Class A, group 2 Software Class (EN62304): B (Moderate Level of Concern)	Risk class (93/42/CE as modified by 2007/47/EEC): IIb Electrical class (EN60601-1): I BF EMC Class (EN60601-1-2): Class A, group 2 Software Class (EN62304): B (Moderate Level of Concern)
Technical features		
Design structure	▪ Generator with RF and MW module, integrated peristaltic pump ▪ Footswitch	▪ Generator with RF and MW module, integrated peristaltic pump ▪ Footswitch
Interface	Monochromatic display touchscreen	Monochromatic display touchscreen
Input AC power supply	100-240 Vac / 50-60Hz 600VA	100-240 Vac / 50-60Hz max 500VA
Fuses	2 x F6.3AL 250V 5x20mm	2 x T5A, 5x20, 250V
Protection, alarms and safety features	Immediate suspension and disabling of microwave and / or radio frequency supply, appropriate acoustic and light signals and display of an appropriate error message on the LCD in the event of: ・ Disconnection of the applicator; ・ Attempt to use incompatible or unrecognized applied parts; ・ Hardware anomalies at the level of the microwave or radio frequency module; ・ Impedance detected between radiofrequency electrode and dispersion plates less than 25 Ohm or greater than 1000 Ohm ・ Anomalies detected by the electrical continuity monitoring circuit of the neutral electrodes. ・ Excessive reflections on the microwave coaxial line	Immediate suspension and disabling of microwave and / or radio frequency supply, appropriate acoustic and light signals and display of an appropriate error message on the LCD in the event of: ・ Disconnection of the applicator; ・ Attempt to use incompatible or unrecognized applied parts; ・ Hardware anomalies at the level of the microwave or radio frequency module; ・ Impedance detected between radiofrequency electrode and dispersion plates less than 25 Ohm or greater than 1000 Ohm ・ Anomalies detected by the electrical continuity monitoring circuit of the neutral electrodes. ・ Excessive reflections on the microwave coaxial line Hardware / software protections added to the aforementioned software protections: ・ Availability of a button (Output Enable) with direct action, that is not mediated by the software, for the emergency stop of the energy supply. ・ The Brown Out Detection circuit is activated on the CPUs that govern the control electronics: in the event of disturbances on the power supply such as to bring the DC voltage applied to the CPUs below a fixed threshold (2.7V), the reset is forced of the machine after a few ms, deactivating the energy supply

	Hardware / software protections added to the aforementioned software protections: ・ Availability of a button (Output Enable) with direct action, that is not mediated by the software, for the emergency stop of the energy supply. ・ The Brown Out Detection circuit is activated on the CPUs that govern the control electronics: in the event of disturbances on the power supply such as to bring the DC voltage applied to the CPUs below a fixed threshold (2.7V), the reset is forced of the machine after a few ms, deactivating the energy supply ・ Filtering grid applied to the bottom surface of the cabinet, to prevent the entry of dust and other foreign bodies.	・ Filtering grid applied to the bottom surface of the cabinet, to prevent the entry of dust and other foreign bodies.
Mechanical features – Dimensions	Width 47 cm (18,5 in) x Depth 35 cm (13,8 in) x Height 13 cm (5,1 in); Bending tips applied to the cabinet bottom lid and lateral strap handle for easy transportation and field placing.	Width 47 cm (18,5 in) x Depth 35 cm (13,8 in) x Height 13 cm (5,1 in) Bending tips applied to the cabinet bottom lid and lateral strap handle for easy transportation and field placing.
Mechanical features – Weight	• AGN-H-1.3: 13 Kg (28.5 lbs) • AGN-3.3: 10.5Kg (23 lbs)	• AGN-H-1.2: 13 Kg (28.5 lbs) • AGN-3.2: 10.5Kg (23 lbs)
Measurements	•Measurements of forward and reflected microwave power and dissipated power on radio frequencies. Measurement range: 1-200W. Accuracy equal to ± 20% for powers> 10W and even to ± 2W for powers less than 10W •Radio frequency load impedance measurements. Measurement range: 10- 1500 Ohm. Accuracy of ± 20% •Temperature measurements: Measurement range: 10-150° C. Accuracy equal to ± 3 °C.	•Measurements of forward and reflected microwave power and dissipated power on radio frequencies. Measurement range: 1-200W. Accuracy equal to ± 20% for powers> 10W and even to ± 2W for powers less than 10W •Radio frequency load impedance measurements. •Measurement range: 10- 1500 Ohm. Accuracy of ± 20% •Temperature measurements: Measurement range: 10-150° C. Accuracy equal to ± 3 °C.
Radiofrequency applicator connection	Yes for AGN-H-1.3, not for AGN-3.3	Yes for AGN-H-1.2, not for AGN-3.2
Cooling system management	Automatic or manual	Automatic or manual
Treatment time range (min)	Up to 15	Up to 15
Microwave and radiofrequency emission features		
Microwave output power	250 W CW max	190 W CW max
Microwave Output frequency	2450 MHz	2450 MHz
Radiofrequency Output Power	200W @ 50 Ohm	200W @ 50 Ohm
Radiofrequency Output frequency	450 kHz	450 kHz
Max nominal voltage	100 Vrms	100 Vrms
Max current	2 Arms	2 Arms

Microwave power delivery control	Continuous or Pulsed	Continuous or Pulsed
Maximum Microwave power in continuous mode	80W	80W
Maximum Microwave power in pulsed mode	180W (duty cycle 40% on - 60% off = 72W)	140W (duty cycle 40% on - 60% off = 56W)
Radiofrequency power delivery control	Manual or automatic or with temperature control	Manual or automatic or with temperature control
Radiofrequency power output mode	Monopolar	Monopolar
Operative impedance range (Ω)	From 25 to 1000	From 25 to 1000
Microwave applicators features		
Microwave applicator needle diameter (Gauge)	17-18	11-14-16
Microwave applicator lengths (mm)	70-100-150	150-200-270
Material in contact with the tissue	Polytetrafluoroethylene (PTFE)	Polytetrafluoroethylene (PTFE)
Conditions of use of applicators	Sterile – disposable	Sterile – disposable

None of the performance or technological differences between the new HS AMICA family devices and the identified predicate devices raises new questions of safety and effectiveness.

7. Performance Data

Subject devices have been subjected to validation testing for electrical safety, electromagnetic compatibility and software verification and validation. These tests verified and validated the proper operation and the performance of the system. The new applied parts of the system are represented by new AMICA PROBE applicators characterized by a smaller diameter compared to already authorized probes. The materials used to manufacture them are the same of the already authorized devices (K182605). These applied parts are provided in sterile condition, which was revalidated.
This present in 8. Conclusion.

Biocompatibility

Biocompatibility testing was not necessary, as the proposed devices are manufactured using the same materials of predicate devices.

Electrical safety and Electromagnetic compatibility

The HS AMICA family generators, AMICA-GEN AGN-3.3 and AGN-H-1.3, have been tested for electrical safety according to IEC 60601-1, IEC 60601-2-6 and IEC 60601-2-2 and for electromagnetic compatibility (EMC) according to IEC 60601-1-2. They comply with all of the medical electrical safety and electromagnetic compatibility requirements.

Software verification and validation

The software of the HS AMICA devices family has been validated according to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices requirements FDA– May 2005 and IEC 62304, and it demonstrated to be safe and effective for its intended use. The software is a Moderate Level of Concern as per FDA guidance. All required items related to software by FDA guidance and modified with respect to the original Submission have been included in this submission.

The changes introduced to adapt the functioning of the software to the new applicators can be considered marginal and therefore only a few validation tests have been performed and only the

documents involved in the changes have been updated with respect to those of the previous Submission (K182605).
It is believed that the documentation developed in recent years up to now can be considered consistent also in the light of the new Guideline “Content of Premarket Submission for Device Software Function” issued on June 14, 2023.

Performance bench testing
Hs Hospital Service Spa conducted an ex-vivo test in order to validate the functional ablation performances of the new 18G-gauge AMICA-PROBE applied part. This new probe represents the thinnest of the applicators present in this family. The measurements performed support the use of the “moving shot” technique, which best suits the thin probes operation.

8. Conclusions

The technological comparison and performance test data provided in this submission support the conclusion that the new HS AMICA devices, generator AGN-H-1.3, generator AGN-3.3 and AMICA-PROBE applicators 17G and 18G, are substantially equivalent to their predicate devices for requested indications for use.