July 14, 2022

Agnes Medical CO., LTD
% DongHa Lee
Regulatory Affairs Consultant
KMC, Inc.
Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu
Seoul, 08375
Korea, South

Re: K203013
Trade/Device Name: Agnes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 13, 2022
Received: July 13, 2022

Dear DongHa Lee:

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,

Colin Keijing Chen, Ph.D.
Acting 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)*
K203013

Device Name
AGNES

Indications for Use *(Describe)*
AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

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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K203013 510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 6, 2022

1. Applicant / Submitter

AGNES MEDICAL CO., LTD

Address: (Seohyeon-dong, 4, 5F Cocoplaza), 20, Seohyeon-ro 210beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea (Postal code: 13591)

Tel : +82-31-8020-9702 Fax : +82-31-701-5162

2. Submission Contact Person

DongHa Lee (RA Consultant / KMC, Inc.)

Address: Room no. 1709, 123, Digital-ro 26-gil, Guro-gu, Seoul, Korea

Tel : +82-70-8965-5554 Fax : +82-2-2672-0579

Email: dhlee@kmcerti.com

3. Device Information

- Trade Name: AGNES
- Common Name: RF Electrosurgical Device
- Classification Name: Electrosurgical cutting and coagulation device and accessories
- Classification Product Code and Regulation: GEI, 21CFR 878.4400
- Subsequent Product Code and Regulation: KCW, 21CFR 878.5350
- Device Class: 2

4. Legally Marketed (Existing) Device

- Trade Name: AGNES (K192728)

5. Description

AGNES is a RF electrosurgical device. It consists of LCD screen, radiofrequency generator and SMPS. The accessories are a footswitch, a hand-piece, single use needle type RF electrodes and FDA cleared Disposable neutral electrode pad (K102372).

6. Indication for use

AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

7. Comparison of the modified device to the cleared device

The following comparison table is presented to demonstrate substantial equivalence.

Descriptive Information		Cleared Device	Modified Device
Manufacturer		AGNES MEDICAL CO., LTD	AGNES MEDICAL CO., LTD
Device Name		AGNES	The same (No change)
510(k) number		K192728	-
Classification Product Code / Regulatory Number		GEI / 878.4400	The same (No change)
Subsequent Product Code		KCW / 878.5350	The same (No change)
Regulatory Class		2	The same (No change)
Indications for Use		AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	The same (No change)
Prescription or OTC		Prescription	The same (No change)
Operation		The device uses RF energy delivered through micro needle electrode to apply heat to target tissue for coagulating.	The same (No change)
Electrosurgical Unit (ESU)	Monopolar or Bipolar	Monopolar	The same (No change)
	Temperature sensors	None	The same (No change)
	Impedance monitor	None	The same (No change)
	Continuity monitor	Checking the connection between the neutral electrode and the electrosurgical unit.	The same (No change)
	Electrode monitor	Provide a camera to monitor the electrode coating condition and shape before using by the user.	The same (No change)
	Waveform	Oscillating rectangular wave	The same (No change)
	Output frequency	1MHz	The same (No change)
	Output operating time	Min 50ms / Max 2,000ms	The same (No change)
	Output power levels	25 levels (2 to 46 W)	The same (No change)
	Max. output power	46 W at 200 ohm	The same (No change)
	Max. output voltage	104V	The same (No change)
	Dimensions	290mm(W)x455mm(L)x271.7mm(H)	The same (No change)
	Weight	5.8Kg	The same (No change)
	Power Input	100-250VAC, 50-60Hz, 280VA	100-240VAC, 50-60Hz, 420VA
	RF Handpiece for the needle	It is connected with the electrosurgical unit.	Connector color changed from yellow to green

	type RF electrode	It transfers the radiofrequency energy through the Single use RF electrode (Needle type)	
	RF Handpiece for the rounded electrode type RF electrode	No existed	New addition
Active accessory (RF Electrode)	Needle type	510(k) cleared by FDA (K171707)	The same (No change)
	Rounded electrode type	No existed	New addition (Models: AG-CN-23G)
Neutral electrode pad	FDA Approval	510(k) cleared by FDA (K102372)	The same (No change)
Miscellaneous accessory (Foot switch)	Functions	For emitting RF energy into electrode.	The same (No change)
	Performance Specifications	Single pole, single throw	The same (No change)
	Physical Specification	Single pedal, IPX6	Single pedal, IPX8

Justification of the Changes

1. Electrosurgical Unit (ESU) – Power Input Specification

   : The power input specification of the Electrosurgical Unit (ESU) is changed.

   - Existed specification: 100-250VAC, 50-60Hz, 280VA
   - Changed specification: 100-240VAC, 50-60Hz, 420VA

   The change was tested for the electrical safety and electromagnetic according to the FDA recognized standards, IEC 60601-1, IEC 60601-2-2 and IEC 60601-1-2.

2. Active accessory (RF Electrode) – Connector Color

   : The connector color of the RF electrode is changed.

   - Existed connector color of the RF electrode: yellow
   - Changed connector color of the RF electrode: Green

3. New additional type RF electrode and RF Handpiece

   : Rounded electrode type RF electrode and RF Handpiece for it are added.

   - Existed device: Only micro needle type RF electrode and handpiece.
   - Modified device: Addition of rounded electrode type RF electrode and handpiece

   The new additional type RF electrode and RF Handpiece was tested with the main body for the electrical safety and electromagnetic compatibility according to the FDA recognized standards.

   1) AAMI/ANSI ES60601-1:2005+A1:2012 (IEC 60601-1:2005+A1:2012), Medical Electrical Equipment - part 1: General requirements for basic safety and essential performance
   2) IEC 60601- 2-2:2017, 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
   3) IEC 60601-1-2:2014, Medical electrical equipment - part 1-2: General requirements for

basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests.

8. Biocompatibility

The new additional type RF electrode can be touched with a patient. Biocompatibility tests were conducted to ensure that no risks arise from biological hazards associated with materials of manufacture and the final device.

1) ISO 10993-1: 2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2) ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
3) ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

9. Sterilization

The EO gas sterilization method of the new additional type RF electrode was validated according to the FDA recognized standards. In the validation, SAL (10^{-6}) and EO gas residuals also was verified.

1) ISO 11135:2014 + A1:2018, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
2) ISO 10993-7: 2008+A1:2019, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

10. Performance Testing – Bench Testing

The RF output power testing was performed in accordance with the FDA recognized standard, IEC 60601- 2-2:2017, 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.

11. Performance Testing – Animal Testing

Animal study was performed to assess thermal tissue damage/spread using mini pig tissues. The skin, liver, kidney, and femoral muscle dissected from 3 mini pigs were used for thermal tissue spread experiment. The skin from 1 mini pig was used in the histopathological analysis for thermal tissue damage experiment. Thermal imaging area analysis, the maximum temperature, the time to reach basal temperature, and histopathological analysis were evaluated.

12. Conclusion

The major consideration such as intended use and principle of operation is not changed. The changes (modifications) of the device were verified and validated relevant to electrical safety and electromagnetic compatibility and biocompatibility. Animal test also performed to assess thermal effect. The test results are supported that the device still maintain safety and effectiveness.

We conclude that the modified device is substantially equivalent to the legally marketed (existed) device.