May 4, 2023

Agnes Medical Co., Ltd
% Sanghwa Myung
Regulatory Affair Consultant
E&m
D-1474, 230, Simin-Daero, Dongan-gu
Gyeonggi-do, Gyeonggi-do 14067
Korea, South

Re: K223805
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, KCW
Dated: April 3, 2023
Received: April 3, 2023

Dear Sanghwa Myung:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.04 13:42:12 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K223805

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.

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K223805

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.

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Date 510(k) summary prepared: May 4, 2023

1. **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: II

2. **Predicate Device**
   - Agnes, K203013

3. **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 RF electrodes and FDA cleared Disposable neutral electrode pad (K102372).

4. **Indication for use**

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

5. Comparison of the modified device to the cleared device

The following comparison table is presented to demonstrate substantial equivalence.

Descriptive Information		Predicated Device	Subject Device
Manufacturer		AGNES MEDICAL CO., LTD	AGNES MEDICAL CO., LTD
Device Name		AGNES	AGNES
510(k) number		K203013	K223805
Classification Product Code / Regulatory Number		GEI / 878.4400	GEI / 878.4400
Subsequent Product Code		KCW / 878.5350	KCW / 878.5350
Regulatory Class		II	II
Indications for Use		AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
Prescription or OTC		Prescription	Prescription
Operation		The device uses RF energy delivered through micro needle electrode to apply heat to target tissue for coagulating.	The device uses RF energy delivered through micro needle electrode to apply heat to target tissue for coagulating.
Electrosurgical Unit (ESU)	Monopolar or Bipolar	Monopolar	Monopolar
	Temperature sensors	None	None
	Impedance monitor	None	None
	Continuity monitor	Checking the connection between the neutral electrode and the electrosurgical unit.	Checking the connection between the neutral electrode and the electrosurgical unit.
	Electrode monitor	Provide a camera to monitor the electrode coating condition and shape before using by the user.	Provide a camera to monitor the electrode coating condition and shape before using by the user.
	Waveform	Oscillating rectangular wave	Oscillating rectangular wave
	Output frequency	1MHz	1MHz
	Output operating time	Min 50ms / Max 2,000ms	Min 50ms / Max 2,000ms
	Output power levels	25 levels (2 to 46 W)	25 levels (2 to 46 W)
	Max. output	46 W at 200 ohm	46 W at 200 ohm

	power		
	Max. output voltage	104V	104V
	Dimensions	290mm(W)x455mm(L)x271.7mm(H)	290mm(W)x455mm(L)x271.7mm(H)
	Weight	5.8Kg	5.8Kg
	Power Input	100-240VAC, 50-60Hz, 420VA	100-240VAC, 50-60Hz, 420VA
	RF Handpiece for the needle type RF electrode	It is connected with the electrosurgical unit. It transfers the radiofrequency energy through the Single use RF electrode (Needle type)	It is connected with the electrosurgical unit. It transfers the radiofrequency energy through the Single use RF electrode (Needle type)
	RF Handpiece for the rounded electrode type RF electrode	It is connected with the electrosurgical unit. It transfers the radiofrequency energy through the Single use RF electrode (Rounded type)	It is connected with the electrosurgical unit. It transfers the radiofrequency energy through the Single use RF electrode (Rounded type)
Active accessory (RF Electrode)	Needle type	510(k) cleared by FDA (K171707)	510(k) cleared by FDA (K171707)
	Rounded electrode type	Models: AG-CN-23G	Add models (AG-CN21G, AG-CN20G, AG-CN19G, AG-CN18G)
Neutral electrode pad	FDA Approval	510(k) cleared by FDA (K102372)	510(k) cleared by FDA (K102372)
Miscellaneous accessory (Foot switch)	Functions	For emitting RF energy into electrode.	For emitting RF energy into electrode.
	Performance Specifications	Single pole, single throw	Single pole, single throw
	Physical Specification	Single pedal, IPX8	Single pedal, IPX8

Rounded electrode type	Model	AG-CN-23G	AG-CN21G	AG-CN20G	AG-CN19G	AG-CN18G
	Diameter (ø)	0.64	0.84	0.90	1.09	1.28
	Rounded Electrode Length	40mm ± 5%	40mm ± 5%			
	Rounded Electrode material	SUS 304	SUS 304			
	Cover tip length	38mm ± 5%	38mm ± 5%			
	Cover tip thickness	9.14mm ± 5%	9.14mm ± 5%			
	Cover tip material	Polycarbonate	Polycarbonate			
	Total length	77.5mm ± 5%	77.5mm ± 5%			

	Sterility	E.O gas Sterilization	E.O gas Sterilization
	Single Use	Single Use	Single Use

- Differences between Subject and Predicates Device

Predicate device's electrode is AG-CN23G. Modified to add electrode AG-CN21G, AG-CN20G, AG-CN19G, AG-CN18G. The each of model's difference is diameter of electrode. Among the same products, the product with the smallest diameter was added to the previous submission, and the remaining electrodes are added this time.

- Discussion

The modifications expressed in this 510(k) Premarket Notification do not change the intended use, nor alter the fundamental scientific technology of the device. The modified devices are as safe and as effective as the predicate device.

6. Biocompatibility

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.

7. Sterilization

The EO gas sterilization method of the additional models 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

8. 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.

9. 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.

Conclusion

The major consideration such as intended use and principle of operation is not changed. Also, it is only adding more models of rounded electrode. The changes (modifications) of the device were verified and validated with biocompatibility of material. We conclude that the modified device is substantially equivalent to the legally marketed (existed) device.