August 19, 2025

Agnes Medical Co., Ltd
% Sanghwa Myung
Regulatory Affair Specialist
E&m
D1474, PyeongCheon Arco Tower, 230, Simin-Daro, Dongan-gu
Anyangsi, Gyeonggi 14067
Korea, South

Re: K243713
Trade/Device Name: RF Electrosurgical Device (RFMagik)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 18, 2025
Received: July 21, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2025.08.19 18:17:02 -04'00'

James Jang, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243713

Device Name

RF Electrosurgical Device (RFMagik)

Indications for Use *(Describe)*

RO handpiece, AGNES (F) RF handpiece and AGNES (B) RF handpiece of RFMagik are intended for use in dermatologic 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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510(k) Summary – Traditional 510(K)

The assigned 510(k) Number: K243713
01. Date of Submission: July 18, 2025

02. Applicant / Submitter

AGNES MEDICAL CO.,LTD
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03. Submission Correspondent

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04. Proposed Device Identification

Device Identification and Regulatory information

1) Proposed Device Identification

- Product Name: RF Electrosurgical Device
- Trade Name (Model): RFMagik
- Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Regulation Number: 21 CFR 878.4400
- Device Class: Class II
- Product Code: GEI
- Review Panel: General & Plastic Surgery

2) Predicate Device Identification

- 510(k) Number: K242469
- Product Name: RF Electrosurgical Device
- Trade Name (Model): RFMagik Lite
- Manufacturer: AGNES MEDICAL CO., LTD.
- Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Regulation Number: 21 CFR 878.4400
- Device Class: Class II
- Product Code: GEI
- Review Panel: General & Plastic Surgery

3) Reference Device identification

- 510(k) Number: K223805
- Device Name: AGNES
- Manufacturer: AGNES MEDICAL CO., LTD.
- Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
- Regulation Number: 21 CFR 878.4400
- Device Class: Class II
- Product Code: GEI, KCW
- Review Panel: General & Plastic Surgery

05. Device Description

RFMagik is a medical device combined with RF current, to function as an electrosurgical device for use in dermatology and general surgical procedures. It is possible to select and change modes, parameters, outputs, etc. using the panel on the main body. It consists of the main device, LCD screen, two handpieces, single use electrodes, electrode pad, NE pad cable, food switch.

There are three handpieces. RO handpiece, AGNES (F) RF handpiece and AGNES (B) RF handpiece that delivers RF energy through the disposable electrode in the handpiece.

06. Indication for use:

RO handpiece, AGNES (F) RF handpiece and AGNES (B) RF handpiece of RFMagik are intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

07. Summary of Technological Characteristics Comparison

1) Primary Predicate Device

	Subject device	Predicate device	Compassion Comment
Manufacturer	AGNES Medical Co., Ltd.	AGNES Medical Co., Ltd.	-
Device Name	RFMagik	RFMagik Lite	-
510(k) number	-	-	-
Classification Name	Electrosurgical cutting and coagulation device and accessories (21 CFR Part 878.4400)	Electrosurgical cutting and coagulation device and accessories (21 CFR Part 878.4400)	-
Product code	GEI	GEI	-
Indication for use	RO handpiece, AGNES (F) RF handpiece and AGNES (B) RF handpiece of RFMagik are intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	RO handpiece and AGNES RF handpiece of RFMagik Lite are intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	Same

Handpiece	RO handpiece AGNES (F) RF handpiece AGNES (B) RF handpiece VVIP handpiece	RO handpiece AGNES RF handpiece VVIP handpiece	SE
Mode of operation	Monopolar	Monopolar	Same
Output energy	Radiofrequency	Radiofrequency	Same
Output Frequency	1MHz	1MHz	Same
Rated Input	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz	Same
Output Power	Max. 32W	Max. 32W	Same
Maximum Power Delivered to Patient	Up to 32W (200ohm)	Up to 32W (200ohm)	Same
Impedance	200 ohm	200 ohm	Same
Electrode Needles	1) Multi needle type RO-25S, RO-25D 2) Needle type GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A, AN-B, AN-C, AN-E, AN-I, AN-S, AN-W3A, AN-F3A, AN-IL, AN-SL, AN-W3B, AN-F1A, AN-F3B, AN-B3A, AN-B4A	1) Multi needle type RO-25S, RO-25D 2) Needle type GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A	SE
Electrode type	Micro needle type	Micro needle type	Same
Electrode needle shelf-life	3 years	3 years	Same
Materials	1) Multi needle type Stainless Steel 2) Needle type Stainless Steel + dimer C coating	1) Multi needle type Stainless Steel 2) Needle type Stainless Steel + dimer C coating	Same
Needle length	1) Multi needle type 0.4mm, 1.2mm 2) Needle type 0.8 ~ 5mm	1) Multi needle type 0.4mm, 1.2mm 2) Needle type 0.8 ~ 5mm	Same
Needle thickness	1) Multi needle type 0.2 mm 2) Needle type 0.2 ~ 0.3 mm	1) Multi needle type 0.2 mm 2) Needle type 0.2 ~ 0.25 mm	Different #1
Needle amount	1) Multi needle type 25ea	1) Multi needle type 25ea	Different #2

	2) Needle type 1~4ea	2) Needle type 1~3ea	
Needle configuration/layout,	1) Multi needle type 5X5 (25ea)	1) Multi needle type 5X5 (25ea)	Same
Max insertion depth	1) Multi needle type Max. 1.2mm 2) Needle type Max. 5mm	1) Multi needle type Max. 1.2mm 2) Needle type Max. 5mm	Same
Min insertion depth	1) Multi needle type Max. 0.4 2) Needle type Min. 0.8mm	1) Multi needle type Max. 0.4 2) Needle type Min. 0.8mm	Same

The subject devices are substantially equivalent to the predicate devices with respect to indications for use, mode of operation, output frequency, output maximum power, RF Intensity, RF Duration, some of electrodes. The basic technology of the subject device and predicate device is the same, but the subject device is equipped with two AGNES RF handpieces found in the predicate device. Along with the added handpiece, the type of Electrode has also been added.

Different #1, #2, thickness, amount.

The thickness, and number of electrodes of the subject device are the biggest differences from the predicate device. There are some technical differences, which have been demonstrated to be safe and effective in pre-clinical testing.

2) Reference Device

	Subject Device	Reference Device	Comparison Comment
Manufacturer	AGNES MEDICAL CO.,LTD	AGNES MEDICAL CO., LTD	-
Device name	RFMagik	AGNES	-
510(k) Number	-	K223805	-
Product code / Regulation	GEI 21 CFR 878.4400	GEI 21 CFR 878.4400	-
Classification	Class II	Class II	-
Indication for use	RFMagik is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis	AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	SAME

Prescription or OTC		Prescription	Prescription	SAME
Mode of operation		Monopolar	Monopolar	SAME
Waveform		Oscillating rectangular wave	Oscillating rectangular wave	SAME
Output frequency		1MHz	1MHz	SAME
Output operating time		Min 50ms / Max 2,000ms	Min 50ms / Max 2,000ms	SAME
Output power levels		0~20 levels (0, 2 to 32W)	25 levels (2 to 46 W)	Different #1
Max. output power		0, 2 ~ 32W at 200 ohm	2 ~ 46 W at 200 ohm	Different #2
Electrical Safety Standards Complies		with IEC 60601-1, IEC 60601-1-2, IEC60601-2-2	with IEC 60601-1, IEC 60601-1-2, IEC60601-2-2	SAME
Connected Handpiece		1) RO Handpiece 2) AGNES (F) RF Handpiece 3) AGNES (B) RF Handpiece 3) VVIP Handpiece	One Agnes RF handpiece	Different #3
Connect patient contact electrode tip	Sterilization	EO gas	EO gas	SAME
	Shelf Life	3 Years	3 Years	SAME
	FDA Cleared Tip	1) GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A 2) RO-25S, RO-25D	1) GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A 2) AG-CN18G, AG-CN19G, AG-CN20G, AG-CN21G, AG-CN23G	Different #4
	New Tips	AN-B, AN-C, AN-E, AN-I, AN-S, AN-W3A, AN-F3A, AN-IL, AN-SL, AN-W3B, AN-F1A, AN-F3B, AN-B3A, AN-B4A	N/A	
Neutral electrode pad		510(k) cleared by FDA	510(k) cleared by FDA	SAME
Foot Switch		Single pedal	Single pedal	SAME

The subject devices are substantially equivalent to the predicate devices with respect to indications for use, mode of operation, output energy type, material, type of sterilization, and shelf life.

#1 Output Levels, #2 Max output power

The reference device max output power is 46 W and subject device is 32W that subject device is lower

max outpower. The steps of output levels may vary because they are affected by the max output power. In this difference, the maximum power of the subject device is lower than that of the reference device, but since the basic technology is the same, the subject device is within the power range of the reference device.

#3, #4 Handpiece type and Electrode tip

The reference device has only one handpiece. The subject device has four handpieces. The difference in these handpieces results in different types of electrodes. The tip of the reference device is included in the same handpiece type as the subject device.

Any differences between the Subject device and predicate device have no significant influence on safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate devices. Differences in these characteristics do not in any effect safety and efficacy in evaluating equivalence. There are no significant differences between the Subject device and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics standards. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this

08. Non-clinical Testing Data

1) Biocompatibility

The biocompatibility tests were performed in accordance with the FDA recognized standards,

- ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Test for irritation

2) Sterility

The EO gas sterilization was verified and validated in accordance with the FDA recognized standards

- ISO 11135: 2014, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11138-1:2017, Sterilization of health care products - Biological Indicators – Part 1: General requirements
- ISO 11138-2: 2017, Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
- ISO 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

3) Shelf life

- ISO 11607-1: 2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

4) Performance Testing

AGNES MEDICAL conducted bench testing to assure that the operates safely and within the predefined design specifications.

5) Ex Vivo Study

Ex Vivo testing conducted on three types of tissue – Liver, skin and Muscle under GLP Thermal testing in accordance with FDA's "Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", August 15, 2014

09. Clinical Testing

Clinical testing is not a requirement and has not been performed.

10. Conclusion

The comparison between the subject devices and the predicate devices shows that the indication for use and technological characteristic is substantially equivalent although there are some differences, the performance test reports are supported to the substantial equivalence of the subject device, the performance test reports are provided to demonstrate substantial equivalence of the subject devices. Therefore, we conclude that the different characteristics do not raise different questions of safety and effectiveness, and thus the subject devices are substantially equivalent to the predicate devices.