September 3, 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: K250217
Trade/Device Name: AGNES Ultra
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 10, 2025
Received: August 4, 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.09.03 10:46:19 -04'00'

Colin Kejing Chen
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)*

K250217

Device Name

AGNES Ultra

Indications for Use *(Describe)*

AGNES RF (DL) handpiece, AGNES RF (F) handpiece and AGNES RF (B) handpiece of AGNES Ultra 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
K250217

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

Submitter: AGNES MEDICAL CO., LTD.
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Primary Contact: Sanghwa(Terri) Myung

Date 510(k) summary prepared: August 28th 2025

1. Proposed Device Identification

Product Name: RF Electrosurgical Device

Trade Name (Model): AGNES Ultra

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

Device Name: 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

510(k) Number: K233120

Manufacturer: Chungwoo Co., Ltd.

Device Name: CWM-930S

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification Name: Electrosurgical cutting and coagulation device and accessories

Classification Product Code and Regulation: GEI, 21CFR 878.4400

Device Class: II

4. Device Description

AGNES Ultra is used to coagulate the patient's tissue. AGNES Ultra 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, handpieces, single use electrodes, Neutral electrode pad, NE pad cable, food switch.

RF energy handpiece is AGNES RF (DL) handpieces, AGNES RF (F) handpiece and AGNES RF (B) handpiece.

that delivers RF energy through the disposable electrode in the handpiece.

5. Indication for use

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

6. Summary of Technological Characteristics Comparison

The following comparison table is presented to demonstrate substantial equivalence.

1) Predicate Device

Descriptive Information		Subjective Device	Predicate Device 1
Manufacturer		AGNES MEDICAL CO., LTD	AGNES MEDICAL CO., LTD
Device Name		AGNES Ultra	RFMagik Lite
510(k) number		K250217	K242469
Classification Product Code / Regulatory Number		GEI / 878.4400	GEI / 878.4400
Regulatory Class		II	II
Indications for Use		AGNES RF (DL) handpiece, AGNES RF (F) handpiece and AGNES RF (B) handpiece of AGNES Ultra 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.
Prescription or OTC		Prescription	Prescription
Mode of Operation		Monopolar	Monopolar
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		0~20 levels (0, 2 to 32W)	0~20 levels (0, 2 to 32W)
Max. output power		0, 2 ~ 32W at 200 ohm	0, 2 ~ 32W at 200 ohm
Negative Pressure		Off, Lv.1~Lv.3 - Off: 0kPa - Lv.1: -25kPa - Lv.2: -35kPa - Lv.3: -45kPa	N/A
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
Connected Handpiece		Four Type of Handpiece 1) AGNES RF (DL) Handpiece 2) AGNES RF (F) Handpiece or AGNES RF (B) Handpiece	Four Type of Handpiece 1) RO Handpiece 2) AGNES RF Handpiece
Connect Patient contact Electrode Tip	Sterilization	EO Gas	EO Gas
	Shelf Life	3 Years	3 Years
	-	1) K223805 (GA-B, GA-C, GA-E, GA-I, GA-S, GA-	1) K171707 (GA-B, GA-C, GA-E, GA-I, GA-S, GA-

		W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A, AG-CN18G, AG-CN19G, AG-CN20G, AG-CN21G, AG-CN23G) 2) K242469 (RO-25S, RO-25D) 3) RO-25S(G), RO-25D(G), ROS-25S(G), ROS-25D(G) 4) 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	W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A) 2) K242469 (RO-25S, RO-25D)
Electrode type		Micro needle type	Micro needle type
Needle thickness		1) GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A : 0.2mm, 0.25mm 2) AG-CN18G, AG-CN19G, AG-CN20G, AG-CN21G, AG-CN23G : 0.64mm(23G) ~ 1.28mm (18G) 2) RO-25S, RO-25D : 0.2mm 3) RO-25S(G), RO-25D(G), ROS-25S(G), ROS-25D(G) : 0.2mm 4) 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 : 0.2mm, 0.25mm, 0.3mm	1) GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A : 0.2mm, 0.25mm 2) RO-25S, RO-25D : 0.2mm
Max insertion depth		5mm	5mm
Min insertion depth		0.4mm	0.4mm
Treatment Area		RO-25S: 8.5mm × 9.3mm RO-25D: 8.5mm × 9.3mm RO-25S(G) : 8.5mm × 9.3mm RO-25D(G) : 8.5mm × 9.3mm	RO-25S: 8.5mm × 9.3mm RO-25D: 8.5mm × 9.3mm

	ROS-25S(G): 8.5mm × 9.3mm ROS-25D(G): 8.5mm × 9.3mm	
Neutral electrode pad	510(k) cleared by FDA (K073360)	510(k) cleared by FDA (K073360)
Foot Switch	Single pedal, IPX8	Single pedal, IPX8

2) Reference Device

	Subject device	Reference Device 1
Manufacturer	AGNES Medical Co., Ltd.	Chungwoo Co., Ltd.
Device Name	AGNES Ultra	CWM-930S
510(k) number	K250217	K233120
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	AGNES RF (DL) handpiece, AGNES RF (F) handpiece and AGNES RF (B) handpiece of AGNES Ultra are intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	This device is intended for use in dermatologic and general surgical procedures for electro coagulation.
Mode of operation	Monopolar	Bipolar and Monopolar
Output energy	Radiofrequency	Radiofrequency
Output Frequency	1MHz	1MHz, 2 MHz
Rated Input	AC 100-240V, 50/60Hz	AC 100-240V, 50/60Hz
Output Power	Max. 32W	1MHz: 35W± 20% (500ohm) 2MHz: 25W± 20% (500ohm)
RF Intensity	1~20 Level	1~10 Level
RF Duration	50ms ~ 2000ms	10ms ~ 900ms
Needles	RO-25S(G) RO-25D(G) ROS-25S(G) ROS-25D(G) RO-25S, RO-25D	25pin (Insulated, Bipolar) 49pin (Non-insulated, Bipolar) 14pin (Non-insulated, Bipolar) 1pin (Insulated, monopolar)

Materials	RO-25S/D: Stainless Steel (STS 304) The others: Stainless Steel (STS 304) + gold coating	Gold coating
Needle length	- RO-25S & RO-25S(G) & ROS-25S(G): 0.4 mm - RO-25D(G) & ROS-25D(G) : 0.4 mm & 0.8 mm - RO-25D: 0.4 mm & 1.2 mm	Bipolar: 0.5mm~3.5mm(14pin, 25pin, 49pin) / 0.5mm~7.0mm(36pin) ±15% / Adjustment unit 0.1mm monopolar: 0.5mm~5.0mm (0.1mm step)
Number of pins	25 pin	Bipolar: RF Microneedle 14pin, 25pin, 36pin, 49pin Monopolar: 1pin
Needle application range	RO-25S: 8.5mm × 9.3mm RO-25D: 8.5mm × 9.3mm RO-25S(G) : 8.5mm × 9.3mm RO-25D(G) : 8.5mm × 9.3mm ROS-25S(G): 8.5mm × 9.3mm ROS-25D(G): 8.5mm × 9.3mm	1pin(1.0 x 1.0mm), 25Pin, 49Pin(7.8 x7.8mm), 14pin(7.8 x 2.0mm), 36pin(11x11mm)
Negative Pressure function	Off: 0kpa Lv.1: -25Kpa (= -0.25bar) Lv.2: -35kPa (= -0.35bar) Lv.3: -45kPa (= -0.45bar) (Only ROS-25S(G), ROS-25D(G))	Max 0.78 bar

- Discussion

The subject devices are substantially equivalent to the predicate devices with respect to indications for use, technology and construction. The differences between the predicate devices and the subject devices are minor and any risks have been mitigated through testing. The different characteristics do not raise different questions of safety and effectiveness.

7. Non-Clinical Testing

1) Electrical Testing and EMC Testing.

The electrical and EMC tests were performed with the compatible radio frequency electrosurgical devices in accordance with the FDA recognized standards,

- AAMI ES60601-1:2005/AMD2:2021, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC60601-2-2:2017/AMD1:2023, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of Radio frequency surgical equipment and Radio frequency.

- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

-TR IEC 60601-4-2: 2024 Medical electrical equipment. Guidance and interpretation. Electromagnetic immunity: performance of medical electrical equipment and medical electrical system

2) 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 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Test for irritation

3) 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

4) 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

- *ASTM F1929-15, Standard test method for detecting seal leaks in porous medical packaging by dye Penetration*

- *ASTM F88M-21, Standard test method for seal strength of flexible barrier materials*

5) Performance Testing

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

6) 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

8. Clinical Testing

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

9. Conclusion

The AGNES Ultra and the predicate device have same indication for use, Technology, mechanism of actions, operational principles and performance for the proposed indications for use.

The non-clinical data for proposed device, including biocompatibility, bench testing, hardware, and software documentation shows that the device should perform as intended in the specified use. In addition, the Electromagnetic Compatibility and Electrical Safety testing shows that the device is safe. 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.