DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 5, 2017

GOWOONSESANG Cosmetics Co., Ltd
% DongHa Lee
Regulatory Affairs Consultant
KMC, Inc.
Room No. 409, ACE Technotower 1-Cha, 38-9,
Digital-ro 31-gil, Guro-gu
Seoul, Korea 152-766 KR

Re: K160469
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: November 4, 2016
Received: November 8, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160469

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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510(k) Summary (K160469)

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

Date: January 3, 2017

1. Applicant / Submitter

GOWOONSESANG COSMETICS CO., LTD
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2. Submission Contact Person

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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, 21CFR878.5350
- Device Class: 2

4. Predicate Device

-	Predicate Device(1)	Predicate Device(2)
Manufacturer	Jeisys Medical Incorporated	IME Co., Ltd.
Device Name	INTRAcel Premium Fractional RF Micro Needle (FRM) System	HR-5000
510(k) number	K153727	K881276

5. Description

AGNES is a RF electrosurgical device. It consists of LCD screen, radiofrequency generator and SMPS. The accessories are a hand-piece, Single use RF electrodes (needle type), Disposable

neutral electrode pad and a footswitch.

6. Indication for use

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

7. Substantial Equivalence

AGNES is substantially equivalent to the predicate device, HR-5000 (K881276) by IME Co., Ltd. The following comparison table is presented to demonstrate substantial equivalence.

Descriptive Information		Subject Device	Predicate Device (1)	Predicate Device (2)
Manufacturer		Gowoonsesang Cosmetics Co., Ltd.	Jeisys Medical Incorporated	IME Co., Ltd.
Device Name		AGNES	INTRAcel Premium Fractional RF Micro Needle (FRM) System	HR-5000
510(k) number		K160469	K153727	K881276
Classification Product Code / Regulatory Number		GEI / 878.4400	GEI / 878.4400	KCW / 878.5350
Subsequent Product Code		KCW / 878.5350	-	-
Regulatory Class		2	2	1
Indications for Use		AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	INTRAcel Premium Fractional RF Micro Needle (FRM) System device is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	Epilation. Dermatologic indications, specifically: telangiectasia, port wine stain, adenoma sebaceum, angiokeratoma, angioma, nevus cell nevi, syringoma, acne, rosacea, senile ectasia, rhinophyma, and lymphangiomas.
Prescription or OTC		Prescription	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.	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	Bipolar	Monopolar
	Temperature sensors	None	None	None

	Impedance monitor	None	None	None
	Continuity monitor	Checking the connection between the neutral electrode and the electrosurgical unit.	None	Unknown
	Electrode monitor	Provide a camera to monitor the electrode coating condition and shape before using by the user.	None	None
	Output frequency	1MHz	1MHz	1MHz
	Waveform	Oscillating rectangular wave	Unknown	Oscillating rectangular wave
	Power output	2 to 46 W at 200 ohm	12.5 to 50W at 200 ohm	5 to 50W at 200 ohm
	Voltage output	25 to 104V	Unknown	10 to 90V
	Dimensions	290mm(W)x455mm(L) x271.7mm(H)	350mm(W)x405mm(L) x1080mm(H)	247mm(W)x270mm(L) x127mm(H)
	Weight	5.8Kg	63Kg	5.2kg
	Power Input	100-250VAC, 50-60Hz	120VAC, 50/60 Hz	100-240VAC,
Active accessory (RF Electrode)	FDA Approval	None	None	None
	Monopolar or Bipolar	Monopolar	Bipolar	Monopolar
	Electrode type	Micro Needle type	Micro Needle type	Micro Needle type
	Physical Dimensions	Needle length : 0.8/1.25/1.5/ 2.0 mm Thickness : 0.2mm	Needle length : 0.5/0.8/1.5/2.0mm Thickness : 0.25mm	Needle length: 1.5mm
	Materials	Electrode: STS 304, Insulating Coating: p-xylylene dimer C	ABS + SUS304	Material: STS 304, Insulating Coating: Teflon PTFE
	Single Use or Reusable	Single Use	Single Use	Single Use
	Sterilization	EO gas	EO gas	EO gas
Neutral electrode pad	Approval	510(k) cleared by FDA (K102372).	None	Unknown
	Conductive or Capacitive	Conductive area: 132cm^2	None	Unknown
	Single Use or Reusable	Single Use	None	Unknown
	Physical Specifications	Mono-polar	None	Mono-polar

	Materials	Conductive material: Metal foil Backing material: Foam backing	None	Metal plate
Miscellaneous accessory (Foot switch)	Functions	For emitting RF energy into electrode.	For emitting RF energy into electrode.	For emitting RF energy into electrode.
	Performance Specifications	Single pole, single throw	Single pole, single throw	Single pole, single throw
	Physical Specification	Single pedal, IP68	Single pedal, IPX8	Single pedal, Unknown
	Materials	Plastic, SPCC	Unknown	Plastic, SPCC

7.1 The same between the subject device and the predicates device.

1) Product Code

: The proposed product code of the subject device is GEI for electrosurgical function. It is the same product code as the predicate device in K153727. The proposed product also has subsequent product code as KCW for epilation function. It is the same product code as the predicate device in K881276.

2) Regulatory number and classification

: The proposed regulatory number of the subject device is 878.4400 and the classification is 2. It is the same regulatory number and classification as the predicate device in K153727.

3) Indications for Use

: The subject device is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. It is the same as the predicate device in K153727.

4) Prescription Use

: The subject device is a prescription use device. It is the same as the predicate devices in K153727 and K881276.

5) Operation

: The principle of operation of the subject device is using RF energy delivered through micro needle electrode to apply heat to target tissue for coagulating. It is the same as the predicate devices in K153727 and K881276.

6) Technical characteristic

: The subject device is monopolar function. It is the same as the predicate device in K881276.
The subject device has 1MHz frequency output. It is the same as the predicate devices in K153727 and K881276.

7) Electrode

: The subject device uses disposable sterilized needle type electrode to delivery RF energy to the

target tissue. It is the same as the predicate devices. For monopolar function, the subject device uses a neutral electrode to be attached the patient back. It is the same as the predicate device in K881276.

8) Miscellaneous accessory
: The subject device uses a footswitch (Single pole, single throw) to emit RF energy into electrode. It is the same as the predicate devices.

7.2 Differences between Subject and Predicates Devices
1) ESU
: The subject device has different RF output power (2 to 46 W). The range of output power is within the predicate devices and the output was also evaluated by safety and performance tests according to IEC 60601-1, IEC 60601-2-2 and animal testing. The results show that these difference does not raise any problems in the safety and effectiveness.

2) Electrode
: The subject device has different electrode physical dimensions (Needle length: 0.8/1.25/1.5/ 2.0 mm, Thickness: 0.2mm). The target tissue is located in dermis (average depth from 0.5mm to 2.0mm). The predicate devices (needle length 0.5/0.8/1.5/2.0mm in K153727, 0.5 to 2.0 mm in K12336 and 1.5mm in K881276) also has target tissue located in dermis. The electrode is coated by different insulating coating material p-xylylene dimer C. Thermal effect was evaluated by animal testing. The results show that these difference does not raise any problems in the safety and effectiveness.

8. Electrical Safety and Electromagnetic compatibility

The Electrical Safety and Electromagnetic compatibility tests were performed in accordance with the following standards.

- IEC 60601-1: 2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-2: 2009, 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, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

9. Performance Testing - Nonclinical

9.1 Electrosurgical Unit

1) RF output power testing

The tests were performed in accordance with the FDA recognized standard, IEC 60601-2-2:2009, Part 2-2: Particular requirements for the basic safety and essential performance of Radio frequency surgical equipment and Radio frequency, Clause 201.11 and 201.12

9.2 Active Component - Disposable RF electrode (Needle type)

1) Mechanical testing (mechanical failure and short circuiting)

2) Electrical performance (insulation integrity)

The tests were performed with the RF surgical unit in accordance with the FDA recognized standard,

- IEC 60601-2-2:2009, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of Radio frequency surgical equipment and Radio frequency, Clause 201.8, 201.13 and 201.15

3) Biocompatibility

The 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: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

4) Sterility and packing

The sterilization and packing is verified and validated in 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 11138-2: 2006, 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
- ISO 11607-1: 2006, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM F1980-07: 2011, Standard guide for accelerated aging of sterile barrier systems for medical devices.

9.3 Disposable Neutral Electrode Pad

The disposable neutral electrode pad is received prior 510(k) clearance by FDA (K102372).

1) Thermal performance, contact impedance, and adhesion testing

The tests were performed with the RF electrosurgical unit in accordance with the FDA recognized standard,

- IEC 60601-2-2:2009, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of Radio frequency surgical equipment and Radio frequency, Sub-clause 201.15.101.

9.4 Miscellaneous component - Foot Switch

1) Design specification and performance test.

The tests were performed with the RF electrosurgical unit in accordance with the FDA recognized standard,

- IEC 60601-2-2:2009, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of Radio frequency surgical equipment and Radio frequency, Sub-clause 201.8.10.4. 201.11.6.5 and 201.12.2

10. Performance Testing - Animal

This animal study was conducted to measure the penetration depth and do a macroscopic check on the improvement of acne and histological pathology analyses on the animal model of acne through clinical assessment (photo assessment) and histological evaluation.

1) Microscopic assessment

- Macroscopic assessment by dermatologist on damage and safety on the skin surface and inside the corium

- Photo taking with a camera (EOS D3000, Cannon, Tokyo, Japan)

- Check the skin conditions using a folliscope magnifying glass (LeedM, Seoul, Korea)

- Assess reduction of acne lesion using 3 dimensional measuring instrument PRIMOS Pico (GFM, Germany)

2) Historical assessment

Extract skin on the rabbit's ear at the end of the test and fix with a 4% paraformaldehyde. Dehydrate with alcohol and xylene by stage and embed with paraffin. Make a fragment of 5㎛ or smaller using a microtome, and remove paraffin with alcohol and xylene again. Dye with hematoxylin & eosin and check the condition of the epidermis and dispersion of sebaceous glands.

This animal study results as the below.

1) We checked the depth of skin penetration and discovered that the penetration depth was relatively accurate. For mini pigs, we found distinct coagulation of skin on the area applied with RF.

2) In order to make the rabbit's ear model, we conducted intradermal injection of acne bacteria P. acnes and induced oleic acid for 4 weeks. As a result, we found acne lesions such as closed comedos and papules or pustules.

3) We selected groups by each grade and conducted the Agnes treatment, and discovered that the sebaceous glands were destroyed and inflammatory cells, papule and pustule on the lesion area were greatly reduced.

4) The destruction of sebaceous glands by Agnes killed acne bacteria and induced fast relief of inflammation, and helped quick treatment that it is considered as a valid method to prevent reoccurrence.

11. Conclusion

In comparing between the subject device and the predicate devices, there are the same indications for use, the operating principle and technological characteristics (monopolar function, output frequency). Although there are some differences as output power, electrode physical dimensions and electrode insulating coating material, the safety and performance test reports are supported to the safety and effectiveness of the subject device. The result of animal study is also supported to thermal effects on tissue and the intended use of the subject device.
In this regard, we conclude that the subject device is substantially equivalent to the predicate devices.