DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 8, 2017

Gowoonsesang Cosmetics Co., Ltd.
c/o DongHa Lee
KMC, Inc.
Room No.904, 27,Digital-ro 27 ga-gil, Guro-gu
Seoul, Korea 08375

Re: K171707
Trade/Device Name: GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A
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, 2017
Received: June 15, 2017

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" (21CFR 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 -S3

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)*

K171707

Device Name
Single Use RF electrode (Needle Type)
(Model: GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A)

Indications for Use *(Describe)*
The Single Use RF electrode (Needle Type) is a monopolar electrosurgical electrode indicated for coagulation of soft tissue when it used in conjunction with compatible radio frequency electrosurgical device.

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

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

Date: July 18, 2017

1. Applicant / Submitter

GOWOONSESANG COSMETICS CO., LTD
Address: (Seohyeon-dong, 4, 5F Cocoplaza), 20, Seohyeon-ro 210beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, 13591, Korea
Tel: +82-31-724-9009 Fax: +82-31-724-9093

2. Submission Contact Person

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Email: dhlee@kmcerti.com

3. Device Information

Trade Name	GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B or GA-F1A
Common Name	Single Use RF Electrode (Needle Type)
Classification Name	Electrosurgical cutting and coagulation device and accessories
Classification Regulation	21CFR878.4400
Device Class	2
Product Code	GEI

4. Predicate Device

Manufacturer	Modern Medical Equipment Manufacturing Limited
Device Name	Disposable General Electrode
510(k) number	K152059

5. Description

Single Use RF Electrode (Needle Type) consists of conductive electrode part, insulation coated part and conductive post part. There are several models (Models: GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A) according to the total size and needle electrode part size.

The conductive post of electrode is inserted into the head of the intended handpiece to receive the radio frequency current and delivers the current to a target tissue for coagulation in electrosurgical procedure. This device is a monopolar RF electrosurgical electrode used in conjunction with radio frequency electrosurgical device and a neutral electrode plate which complies with IEC 60601-1 and IEC 60601-2-2. It is intended to be used exclusively with the ESU cleared in K160469, Model: AGNES.

6. Technological Characteristic

The proposed Single Use RF Electrode (Needle Type) is a stainless steel (STS 304) coated by electrical insulation material, p-xylylene dimer C. The conductive electrode part is shaped as needle and the other end as conductive post part is inserted into the head of the intended handpiece to receive the radio frequency current from radio frequency generator.

The conductive electrode part delivers radio frequency current onto a target tissue for coagulation during an electrosurgical procedure. The insulation material prevents accidental conduction of the electrosurgical current from this point to the patient. The construction of proposed electrode and the predicted device is identical. There are no new questions raised regarding to effectiveness and safety.

7. Intended Use / Indication for use

The Single Use RF electrode (Needle Type) is a monopolar electrosurgical electrode indicated for coagulation of soft tissue when it used in conjunction with compatible radio frequency electrosurgical device.

8. Substantial Equivalence

Single Use RF electrode (Needle Type) is substantially equivalent to the predicate device, Disposable General Electrode (K152059) by Modern Medical Equipment Manufacturing Limited. The following comparison table is presented to demonstrate substantial equivalence.

Descriptive Information	Subject Device	Predicate Device
Manufacturer	GOWOONSESANG COSMETICS CO., LTD.	Modern Medical Equipment Manufacturing Limited
Device Name	Single Use RF electrode (Needle Type) (Model: GA-B, GA-C, GA-E, GA-I, GA-S, GA-W3A, GA-F3A, GA-IL, GA-SL, GA-W3B, GA-F1A)	Disposable General Electrode
510(k) number	-	K152059
Product Code	GEI	GEI
Regulatory Class	2	2
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Indications for Use	The Single Use RF electrode (Needle Type) is a monopolar electrosurgical electrode indicated for coagulation of soft tissue when it used in conjunction with compatible radio frequency electrosurgical device.	The electrode is used to cut and / or coagulate soft tissues by means of high frequency electrical current during an electrosurgical procedure.
Prescription or OTC	Prescription	Prescription
Monopolar or Bipolar	Monopolar	Monopolar
Materials	Stainless Steel (STS 304),	Stainless Steel (Unknown),
Insulating Coating	p-xylylene dimer C	Polyolefin Shrink Wrap, Teflon Shrink Wrap or ABS/HIPS
Single Use or Reusable	Single Use	Single Use
Sterilization	EO gas	EO gas
Packing	Blister film and Blister paper	Unknown
Shelf life	3 years	Unknown

8.1 The same between Subject device and Predicate Device.

1) Product Code

: The product code of the subject device is GEI. It is the same product code as the predicate device.

2) Regulatory Class

: The classification of the subject device is 2 according to the product code, GEI. It is the same classification as the predicate device.

3) Indications for Use

: The indications for use of the subject device is indicated for coagulation of soft tissue. It is the same indications for use as the predicate device. In the K152059, the predicate device is indicated to cut and / or coagulate soft tissues by means of high frequency electrical current.

4) Prescription Use

: The subject device is a prescription use device. It is the same as the predicate device.

5) Principle of operation

: The principle of operation of the subject device is electrosurgical coagulation by means of radio frequency electrical current when it used in conjunction with compatible radio frequency electrosurgical device. It is the same as the predicate device.

6) Technical characteristic

: The subject device is a disposable monopolar electrosurgical electrode. It is the same as the predicate device.

7) Sterilization.

: The subject device is sterilized by E.O gas. It is the same as the predicate device.

8.2 Difference between Subject device and Predicate Device

1) Material

: Raw material of the subject device is stainless, STS 304. Raw material of the predicate device is also stainless but the characteristic is unknown.

2) Insulation coating

: Insulation coating material of the subject device is p-xylylene dimer C. The predicate device is coated by insulation materials, Polyolefin Shrink Wrap, Teflon Shrink Wrap or ABS/HIPS

3) Packing and shelf life

: The subject device is packed by blister film and blister paper and the shelf life is 3years. Packing and shelf life are unknown.

The subject device has been tested about electrical safety, EMC, bio-compatibility and performance. The packing and shelf life has been verified and validated. The results show that these differences do not raise any problems in the safety and effectiveness.

9. Electrical Testing and EMC Testing

The Single Use RF electrode (Needle Type) is indicated for coagulation of soft tissue when used in conjunction with compatible radio frequency electrosurgical device.

The electrical and EMC tests were performed with the compatible radio frequency electrosurgical devices (Model: AGNES, Cleared in K160469) in accordance with the FDA recognized standards,

- IEC 60601-1:2005/2012, 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 60601-1-2:2007/2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

The test results are met the electrical safety and EMC requirements.

10. Performance Testing - Nonclinical

1) RF output

The RF output test were performed with the compatible radio frequency electrosurgical devices (Model: AGNES, Cleared in K160469) in accordance with the FDA recognized standards, Clause 201.11 and 201.12.

- 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.

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 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and

skin sensitization.

- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

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 11138-1:2006, Sterilization of health care products - Biological Indicators – Part 1: General requirements
- 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

4) Packing and Shelf life

The blister packing and the shelf life was verified and validated in accordance with the FDA recognized standards

- ISO 11607-1: 2006, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 116070-2:2006, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980: 2011, Standard guide for accelerated aging of sterile barrier systems for medical devices.

5) Mechanical retention of detachable active electrodes

The mechanical retention of detachable active electrodes test was performed in accordance with the FDA recognized standard, Clause 201.15.4.1.1 02

- 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.

6) Extractable Substance Test

The extractable substance tests were performed about PH, Potassium permanganate-reducible substances, Residue on evaporation, UV spectrum and Heavy metals.

7) Measurement Tolerance Test

The subject device has several models according to different size. The measurement tolerance tests were conducted about the needle length, body length and thickness of the specified different size.

8) Electrical Current Flow Test

The subject device is a monopolar electrosurgical electrode to flow RF current when it used in conjunction with compatible radio frequency electrosurgical device. The electrical current flow test was conducted through a circuit tester.

The test results are met the performance requirements.

11. Performance Testing - Animal

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

12. Conclusion

In comparing between the subject device and the predicate device, there are the same indications for use, prescription use, the principle of operation and technological characteristics (monopolar, single use, raw material). Although there are some different specifications (material, insulation coating, packing and shelf life), 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 device.