September 8, 2023

Alic Iotech, LLC
Like Zeng
Official Correspondent
8165 Mountain View Dr Unit D
Pleasanton, California 94588

Re: K231146
Trade/Device Name: AliTight
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 21, 2023
Received: August 15, 2023

Dear Like Zeng:

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,

Colin K. Chen -S

for

Mark Trumbore, 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231146

Device Name

AliTight

Indications for Use *(Describe)*

The AliTight device is intended for use in the non-invasive heating of facial skin.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K231146

510(k) SUMMARY

AliTight Device

Applicant's Name: ALIC IOTECH, LLC
8165 Mountain View Dr Unit D
Pleasanton, CA 94588
U.S.A.
Tel. +1 (520) 907-1679

Contact Person: Like Zeng
8165 Mountain View Dr Unit D
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U.S.A.
Tel. +1 (520) 907-1679
Email: soarmichael@gmail.com

Date Prepared: September 6th, 2023

Name of Device: AliTight

Common or Usual Name: Electrosurgical cutting and coagulation device and accessories

Classification: **Product Code:** GEI
Regulation No: 21 C.F.R. §878.4400
Class: II
Classification Panel: General & Plastic Surgery

Predicate Devices: Pollogen Ltd., STOP U (K140255)

Intended Use / Indications for Use

The AliTight device is intended for use in the non-invasive heating of facial skin.

Device Description

The AliTight device delivers RF current into the skin to generate heat through electrical impedance in the dermis and subcutaneous layers. The device consists of the AliTight device and the AliTight power supply.

Comparison of Technological Characteristics

The AliTight device delivers RF energy at a frequency of 1MHz and a maximum output RMS power of 5 watts into the skin through its electrodes. The device generates heat through electrical impedance in the dermis and subcutaneous layers. The temperature sensor, located between the electrodes constantly monitors the skin temperature and disables RF transmission once the desired skin temperature is obtained.

The following table compares the AliTight device to the predicate devices with respect to technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Description	**Proposed Device** **AliTight**	**Predicate Device 1** **STOP U (K140255)**
Class of Device	II	II
Classification Panel	General & Plastic Surgery	General & Plastic Surgery
Regulation Number	21 C.F.R. §878.4400	21 C.F.R. §878.4400
Regulation Description	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Product Code	GEI	GEI
Prescription or OTC	Prescription	Prescription
Deep Tissue Heating Electromagnetic Energy	Radiofrequency (RF)	Radiofrequency (RF)
Mode of Operation	RF Bipolar energy	RF Bipolar energy
RF Carrier Frequency	1 MHz	1 MHz
Waveform	Sinusoid	Sinusoid
Nominal Operating RF Power (200 Ohms)	5W	5.7W
Number of Electrodes	4	4

Description	Proposed Device AliTight	Predicate Device 1 STOP U (K140255)
Dimensions	161mm L x 64mm W x 52mm H	H=134mm; L=51mm; W=32mm
Weight	142gr	85 gr
Energy Source	100 – 240VAC, 50-60Hz, 500mA	100-240V, 50-60Hz, 600mA
Output Voltage	12 V DC	8V DC
Safety Mechanism	The temperature sensor, located between the electrodes constantly monitors the skin temperature and disables/reduces RF transmission once the desired skin temperature is obtained	The temperature sensor, located between the electrodes constantly monitors the skin temperature and disables RF transmission once the desired skin temperature is obtained
Biocompatibility	All parts that are in contact with patient comply with the requirements of ISO 10993-1	All parts that are in contact with patient comply with the requirements of ISO 10993-1
Software	Verified and validated according to the FDA guidance	Verified and validated according to the FDA guidance

Performance Data

ALIC IOTECH conducted several performance tests to demonstrate that the AliTight device complies with performance standards and that it functions as intended.

- Verification test demonstrating that the AliTight device meets the system's technical specifications for the over-heating safety and RF power output.
- The AliTight device software was validated as required.

In all instances the AliTight device functioned as intended and observations were as expected.

Performance Standards

The AliTight device complies with the following performance standards:

- IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance (2005/AMD1:2012)
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests (2014, Ed.4)
- IEC 60601-1-6 Medical Electrical Equipment Part 1-6: General requirements for safety – Collateral Standard: Usability (2010, AMD1:2013, AMD2:2020)

- IEC 60601-1-11 Medical Electrical Equipment Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (2015, Ed.2)
- IEC 60601-2-2 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 (2017, Ed.6.0)
- IEC 62304 Medical device software – Software life cycle processes (2006, Ed. 1/AMD A1:2015)

Conclusion

The subject AliTight device is indicated for non-invasive heating of facial skin. The subject device principles of operation and technological characteristics do not raise new or different questions of safety or effectiveness. The subject device is substantially equivalent to the predicate device.