October 16, 2025

ASTERASYS Co., Ltd.
Chayeon Kim
Head of Regulatory Affairs Team
#1005, #508, #313, 25 Seongsuil-ro 4-gil Seongdong-gu
Seoul, 04781
Korea, South

Re: K250852
Trade/Device Name: Coolfase
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 15, 2025
Received: September 15, 2025

Dear Chayeon Kim:

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: 2025.10.16 15:38:00 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250852

Please provide the device trade name(s).

Coolfase

Please provide your Indications for Use below.

Coolfase is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. General Information [21 CFR 807.92(a)(1)]

Submitter / Applicant:	Contact Person:
ASTERASYS Co., Ltd. Rm 1005, 25 Seongsuil-ro 4-gil, Seongdong-gu, Seoul, 04781 Republic of Korea Tel: +82-2-6953-0456	Dr. Chayeon Kim Rm 1005, 25 Seongsuil-ro 4-gil, Seongdong-gu, Seoul, 04781 Republic of Korea Phone: +82-10-4263-1721 Email: amy.kim@asterasys.com
Preparation Date:	Month 07, 2025

2. Device Name and Code [21 CFR 807.92(a)(2) and (3)]

Device Trade Name:	Coolfase
Common Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Product Code:	GEI
CFR References:	21 CFR 878.4400
Regulatory Class:	II
Predicate Device:	Thermage FLX system
Review Panel:	General & Plastic Surgery

3. Device Description [21 CFR 807.92(a)(4)]

Coolfase is electrosurgical unit that high-frequency current for tissue coagulation during treatment. It consists of an electrosurgical unit main body, a handpiece, and a tip, and is used in conjunction with a grounding pad, coupling gel, and a foot switch. The high-frequency current generated by the main body is delivered to the skin through the handpiece connected to the tip. The electrical resistance of the skin generates heat, and this heat coagulates the tissue.

4. Indications for Use [21 CFR 807.92(a)(5)]

Coolfase is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

5. Summary of Technological Characteristics

Technical Characteristics in Comparison to Predicate Devices [21 CFR 807.92(a)(6)]

Characteristic	Subject Device	Predicate device K170758
Applicant	ASTERASYS Co., Ltd.	Solta Medical, Inc.
Device name	Coolfase	Thermage FLX system
510(k) Number	K250852	K170758
Device Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories	Same
Classification	Class II	Same
Review Panel	General & Plastic Surgery	Same
Classification Product Code	GEI	GEI, ISA
Regulation Number	21 CFR 878.4400	Same
Indications for Use	Coolfase is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis	The radiofrequency-energy only delivery components of the Thermage FLX System are indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis
Prescription or OTC	Prescription	Same
Anatomical Site	Intact skin	Same
Contact duration	Less than 24 hours	Same
Electrode type	Monopolar RF	Same
Frequency	6.78 MHz ± 10 %	6.78MHz ± 0.1%
Input voltage	100-240V, 50/60 Hz, 400VA	100-240V, 50/60 Hz, 10A
Different – VA The proposed device and the predicate device share the same input voltage specification (100–240 V, 50/60 Hz), although their VA ratings differ. The input power of the proposed Coolfase (1400 VA) corresponds to a lower current draw than that of the predicate device (10 A) and remains within the specified input voltage range. Accordingly, this variation does not materially affect the device's safety or effectiveness.		
Maximum output Power	140W	400W
Different – Max output power The Max output power for proposed device is different from the predicate devices. However, the Max output power of the proposed Coolfase is covered by the range of the Max output power of the predicate device. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.		
Mode of Operation	Manual or footswitch	Same
Electrode size	0.25 cm^2 (CF-E tip / CF-CT05) 4.0 cm^2 (CF-F tip / CF-CF20) 16 cm^2 (CF-B tip / CF-CF40)	Same (Thermage FLX is equipped with one additional 3.0 cm^2 tip)
Sterilization	Provided as non-sterile	Same
Number of uses per electrode	Signle use	Same
Weight	20 kg	45 kg
Type & degree of protection against shock	Class 1 / type BF applied part	Same
Dimension	27 cm (W) x 28.9 cm (L) x 115.4 cm (H)	49.5 cm (W) x 43.0 cm (L) x 125.7 cm (H)
User interface	LCD / Touchscreen Technology for user interaction and controls	Same

Demonstrated Safety and Efficacy in treated area	Performance Testing section	Provided in K170758 cleared September 22, 2017
Patient Contact Material	Biocompatible	Biocompatible
Electromagnetic compatibility standards	Compliant	Compliant
Medical electrical equipment Safety standards	Compliant	Compliant

The proposed device, Coolfase, uses a monopolar electrode type, similar to the predicate device, Thermage FLX system. While the maximum output power of Coolfase differs from Thermage FLX, it still falls within the overall power range of the predicate device. This ensures that the difference does not raise new questions regarding safety or effectiveness. Both devices offer the same operational modes, supporting both manual operation and footswitch control, and they share a similar user interface, utilizing LCD touchscreen technology for user interaction and control. Taken together, these similarities demonstrate that Coolfase is substantially equivalent to Thermage FLX in terms of both technological characteristics and intended use.

6. Non-Clinical and/or Clinical Test Summary & Conclusions [21 CFR 807.92(b)]

Thermal performance testing was conducted to evaluate the subject device with respect to the risks of burns and incomplete tissue coagulation. Ex vivo side-by-side testing on tissue was performed comparing the subject device and the predicate device, in accordance with FDA's 'Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery' Guidance (March 2020). The results were further assessed by histological analysis to verify tissue effects and to demonstrate substantial equivalence.