May 15, 2025

WE Medical Technology (Wuxi) Co., Ltd.
Ray Wang
General Manager
D603-2, 530 BLDG, No. 18 Qingyuan RD, Xinwu DIST
Wuxi, Jiangsu 214111
China

Re: K240857
Trade/Device Name: Youmagic FLM System (YM5-U1)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 27, 2024
Received: September 27, 2024

Dear Ray Wang:

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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.05.15 22:32:14 -04'00'

James Jang, 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.

510(k) Number *(if known)*
K240857

Device Name
Youmagic FLM System (YM5-U1)

Indications for Use *(Describe)*
The radiofrequency-energy only delivery components of the Youmagic FLM System are indicated for use in dermatologic surgical procedures for electrocoagulation and hemostasis.
The Youmagic FLM System is a prescription use 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

The assigned 510(k) Number: K240857

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 05/15/2025

2. Sponsor Identification

WE Medical Technology (Wuxi) Co., Ltd.
D603-2, 530 BLDG, No. 18 Qingyuan RD, Xinwu DIST, Wuxi, Jiangsu, PR China
Post Code: 214111
Contact Person: Li Tianmin
Position: Chief Executive Officer
Tel: +86-400-888-099-3
Email: litianmin@wemt.tech

3. Designated Submission Correspondent

Contact Person: Ray Wang
Tel: +86-18910677558
Fax: +86-10-56335780
Email: information@believe-med.com

4. Identification of Proposed Device

Trade Name: Youmagic FLM System
Model: YM5-U1
Common Name: Electrosurgical, Cutting & Coagulation & Accessories

Regulatory Information
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Classification: II
Product Code: GEI
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulation Medical Specialty: General & Plastic Surgery
Review Panel: General & Plastic Surgery

Indication For Use Statement:

The radiofrequency-energy only delivery components of the Youmagic FLM System are indicated for use in dermatologic surgical procedures for electrocoagulation and hemostasis.
The Youmagic FLM System is a prescription use device.

5. Device Description

The Youmagic FLM System delivers RF energy for selective coagulation of tissue while conductively cooling the epidermis. The Youmagic FLM System delivers energy from the disposable tip to the patient. The System and its Handpiece monitor skin contact during treatment. The System employs RF tuning to provide RF energy across a range of impedances for delivery to the patient through single and multiple pass stamping motions of the tip.

The Youmagic FLM System is a monopolar, conductive radiofrequency System designed for use in non-invasive dermatological procedures.

The System consists of the following components: Console, including touchscreen, a Handpiece, Treatment Tip, and AC power cord. The System is used with the following WE Medical-supplied accessories: Cryogen Canister, Return Pad.

The System continuously monitors output power, output energy, treatment duration, and measured impedance.

The System also controls the coolant delivery through the Handpiece. The Handpiece delivers RF energy while cooling tissue by thermal conduction.

6. Identification of Predicate Device(s)

510(k) Number: K170758
Product Name: Thermage FLX System
Manufacturer: Solta Medical Inc.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 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 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- IEC 60601-1:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- ISO 60601-1-2: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-2:2017 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
- IEC /TR 60601-4-2:2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- Thermal effects test on tissue per FDA Guidance - Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Technology Comparison

Item	Proposed Device	Predicate Device (K170758)	Remark
Indications for Use	The radiofrequency-energy only delivery components of the Youmagic FLM System are indicated for use in dermatologic surgical procedures for electrocoagulation and hemostasis. The Youmagic FLM System is a prescription use device.	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; • Non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids; • Non-invasive treatment of wrinkles and rhytids. The simultaneous application of radio frequency energy and skin vibration by the Thermage FLX System is indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis; • Non-invasive treatment of periorbital wrinkles and rhytids; • Non-invasive treatment of wrinkles and rhytids; • Temporary improvement in the appearance of cellulite; • Relief of minor muscle aches and pains; • Relief of muscle spasms; • Temporary improvement of local circulation (i.e., blood circulation).	Different 1

510(k) Summary

Product Code		GEI	GEI, ISA	SAME
Regulation No.		21 CFR 878.4400	21 CFR 878.4400	SAME
Prescription or OTC		Prescription Use	Prescription Use	SAME
User interface		LCD / Touchscreen Technology for user interaction and controls	LCD / Touchscreen Technology for user interaction and controls	SAME
Mode of Operation		Manual	Manual or Footswitch	Different 2
Frequency		6.78 MHz	6.78 MHz	SAME
Monitored parameters		The product is equipped with a cooling system and a temperature detection control system	The product is equipped with a cooling system and a temperature detection control system	SAME
ESU				
Major functions	**Monopolar**	Monopolar	Monopolar	SAME
	Temperature sensors	NTC Sensor	NTC Sensor	SAME
	Impedance monitor	Impedance monitor	Impedance monitor	SAME
	Continuity monitor	Continuity monitor	Continuity monitor	SAME
Performance specifications	**Output frequency**	6.78MHz	6.78MHz	SAME
	Waveform	sine wave	sine wave	SAME
	Max Power output	175W	400W (173W with Total Tip 4.0 cm^2)	Different 3
	Voltage output	Max peak to peak voltage 750Vpp@400Ω	Max peak to peak voltage 770Vpp@400Ω	Different 4
	Crest factor	2.02～4.134	2.007～4.123	Different 4
	Pulse Number	5	5	SAME
	Pulse Width	200ms	200ms	SAME
	Pulse Interval	50ms	50ms	SAME
	duty cycle	0.8	0.8	SAME
	Load resistor range	75Ω～400Ω	75Ω～400Ω	SAME
Treatment Tip				
Monopolar or bipolar		Monopolar	Monopolar	SAME
Treatment Area		Total Tip 4.0cm^2	Total Tip 4.0cm^2 Total Tip 3.0cm^2 Eye Tip 0.25cm^2 Body Tip 16.0cm^2	Different 5
Maximum Average Power		146W	144W±20% with Total Tip 4.0 cm^2	Different 6
Materials	**Electrode**	Cu	Cu	SAME
	Insulation	Polyimide/ABS (Acrylonitrile Butadiene Styrene)	Polyimide/ABS (Acrylonitrile Butadiene Styrene)	SAME

	Coating	/	/	SAME
Return Pad				
Conductive or capacitive		Conductive	Conductive	SAME
Physical specifications (Dimensions)		210mm(L) × 101mm(W)	215mm(L) × 118mm(W)	Equivalent
Materials		Anti-adhesive film, aluminum foil, conductive adhesive, tongue, sponge.	Anti-adhesive film, aluminum foil, conductive adhesive, tongue, sponge.	SAME
Technical specification		R＜50Ω@ (200KHz-5MHz)	R＜50Ω@ (200KHz-5MHz)	SAME

Analysis 1:

The proposed device are different in Intended Use and Indications for Use from the predicate device. However, the Intended Use and Indications for Use of the proposed device are within the range of the predicate device and this minor difference will not raise any issues in safety and effectiveness. By complying with IEC 60601-1 and IEC 60601-2-2, the mechanical performance of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Analysis 2:

The proposed device is different in Mode of Operation from the predicate device. However, this difference is just in physical specification and this difference will not raise any issues in safety and effectiveness. By complying with IEC 60601-1 and IEC 60601-2-2, the mechanical performance of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Analysis 3:

The proposed device is different in Max Power output from the predicate device. Although the max power output of the predicate device is 400W, the max power output under the Total Tip 4.0cm^2 is 173W, while max power output of the proposed device is 175W, so this minor difference will not affect safety and effectiveness of the proposed device.

Analysis 4:

The proposed device is different in Performance specifications (Voltage output and Crest factor) from the predicate device. However, the Performance specifications of the proposed device and predicate device are similar, and these minor difference will not raise any issues in safety and effectiveness. By complying with IEC 60601-1 and IEC 60601-2-2, the mechanical performance of the proposed device is determined to be accepted. Therefore, these difference will not affect safety and effectiveness of the proposed device.

Analysis 5:

The proposed device is different in Treatment Area from the predicate device. However, the Treatment Area of the proposed device is within the range of predicate device and this minor difference will not raise any issues in safety and effectiveness. By complying with IEC 60601-1 and IEC 60601-2-2, the mechanical performance of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Analysis 6:

The proposed device is different in Maximum Average Power from the predicate device. After calculation, $Pavg = Pmax * \frac{\sum_{i=1}^{i=5} Ti}{\sum_{i=1}^{i=5} Ti + \sum_{i=1}^{i=4} ti}$=*Pmax**0.833=175W*0.833≈146W, the max power output of the proposed device is 146W, and predicate device is 144W, so this minor difference will not affect safety and effectiveness of the proposed device. Please refer to section 4.7.7, page 45 of the attachment ESU Performance Testing Report in eSTAR document for a detailed calculation process.

10. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K170758).