April 2, 2026

El.En S.P.A.
Peruzzi Paolo
Regulatory Affairs Manager
Contact Address

Re: K260647
Trade/Device Name: SPECCHIO
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: [NOTE: Use date of most recent supplement]
Received: March 6, 2026

Dear Peruzzi Paolo:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.04.02 16:38:20 -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

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.	K260647

Please provide the device trade name(s).

SPECCHIO

Please provide your Indications for Use below.

The SPECCHIO RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.
The SPECCHIO massage device is intended to provide a temporary reduction in the appearance of cellulite.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

SPECCHIO – Special 510(k)

Submitter:

El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI), Italy

Contact:

Paolo Peruzzi
Regulatory Affairs Manager & Official Correspondent
Phone: +39.055.8826807
E-mail: p.peruzzi@elen.it

Date Summary Prepared:

February 27th, 2026

Device Trade Name:

SPECCHIO

Common Name:

Medical radio frequency and massage device

Regulation Number:

21 CFR 878.4400

Regulation Name:

Electrosurgical cutting and coagulation device and accessories

Regulatory Class:

Class II

Product Code:

PBX

Predicate Device:

DEKA TIAC II (K211091)

Device Description:

The SPECCHIO is a medical device that used high frequency RF currents to produce a localized increase in temperature in subcutaneous tissue, for temporary relief of pain and muscle spasm and increase local

circulation. The device has integrated massaging handpieces intended to provide a temporary reduction in the appearance of cellulite.

The SPECCHIO device electrical specifications are: 100-240V~, 50/60Hz, 1500VA.

The proposed SPECCHIO is a modification of DEKA TIAC II device (K211091)

The modifications to the cleared device are:

- Restyling of the device (chassis, cover plastics and GUI)
- Engineering of the Shallow and Deep handpieces (colour change, profiling and interchangeability of massage head)
- Addition of Pocket PRO handpiece

The technical specifications are within the range of the already cleared predicate device DEKA TIAC II (K211091)

The indications for use of the modified device are unchanged with respect to the predicate device. Labelling itself has been updated also to include general improvements that have been implemented since predicate device clearance and considered as minor changes.

Indications for Use:

The SPECCHIO RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.
The SPECCHIO massage device is intended to provide a temporary reduction in the appearance of cellulite.

Comparison with the Predicate Device:

The SPECCHIO device is as safe, as effective, and performs as well as the legally marketed predicate device DEKA TIAC II (K211091).

Device Trade Name	Subject Device **SPECCHIO**	Predicate Device **K211091** **DEKA TIAC II**	Comment
Indications for use	The SPECCHIO RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The SPECCHIO massage device is intended to provide a temporary reduction in the appearance of cellulite.	The DEKA TIACII RF device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The DEKA TIAC II massage device is intended to provide a temporary reduction in the appearance of cellulite.	Identical
Regulation Number	21 CFR 878.4400: Electrosurgical cutting and coagulation	21 CFR 878.4400: Electrosurgical cutting and coagulation	Identical
Product Code	PBX	PBX	Identical
Device Technologies	Application of the heat to the tissue via RF energy.	Application of the heat to the tissue via RF energy.	Identical

Device Trade Name	Subject Device **SPECCHIO**	Predicate Device **K211091** **DEKA TIAC II**	Comment
	Mechanical Massaging of body parts	Mechanical Massaging of body parts	
Maximum RF output power	200W	200W	Identical
RF mode of operation	Bipolar	Bipolar	Identical
RF Output Frequency	2.45 GHz	2.45 GHz	Identical
Effective temperature	40-43°C	40-43°C	Identical
Contact quality monitoring system	YES	YES	Identical
Handpieces	Deep PRO Handpiece (66 mm) Shallow PRO Handpiece (56 mm) Pocket PRO Handpiece (36.5 mm)	Deep Handpiece (78 mm) Shallow handpiece (68 mm)	Similar Differences do not affect safety and efficacy
Massage handpiece dimensions	68 mm	Handpiece 1: Diameter: 68 mm Handpiece 2: Diameter: 78 mm	Subset
Massage handpiece material	AISI 316	AISI 316	Identical

Clinical Performance Data:

Clinical performance tests, in order to demonstrate that SPECCHIO RF device is capable of maintaining a skin surface temperature of 40º-45ºC for at least 10 minutes when using the device as intended (same test method used for the predicate device).

Non-Clinical Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the SPECCHIO device, according to the following standards:

- ANSI AAMI ES60601-1Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- 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.

- Test according to IEC 60601-2-6:2012+A1:2016- Medical electrical equipment - Part 2-6: Particular requirements for basic safety and essential performance of microwave therapy equipment.
- Non-clinical performance tests on ex-vivo animal tissue, in order to show that SPECCHIO RF device is able to maintain the tissue temperature in the range 40°C - 43°C for at least 5 minutes, at the maximum setting of RF output power (same test method used for the predicate device).

Software Validation and Verification Testing

Software verification and validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions".

Conclusion:

On the basis of the comparison with the predicate devices and on the non-clinical performance data, we can conclude that SPECCHIO device is deemed to be substantially equivalent to the predicate device for the proposed indications for use.

Additional Information:

None.