May 8, 2026

Elde Medikal Sanayi ve Ticaret Anonim Sirketi
Deniz Ozgulbas
Regulatory Consultant
Necip Fazil Bulvari Keyap Carsi Sitesi No: 44
D-1 Blok Dukkan No: 53/2
Umraniye/Istanbul, 34775
Turkey

Re: K253237
Trade/Device Name: Elde Medical Electrodes (T5/ 5 cm x 5cm electrode T10/ 5 cm x 10cm electrode)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: September 28, 2025
Received: September 29, 2025

Dear Deniz Ozgulbas:

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine 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.	K253237

Please provide the device trade name(s).

Elde Medical Electrodes (T5/ 5 cm x 5cm electrode;
T10/ 5 cm x 10cm electrode)

Please provide your Indications for Use below.

The Elde Medical electrode is intended to transmit electrical current to the patient skin for use with transcutaneous electrical stimulation devices. Some common types of the stimulation devices include, but are not limited to TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is for OTC (Over-the-Counter) or Prescription use.

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)

K253237 510(k) Summary

Applicant – 510(k) Owner

Name: Elde Medikal Sanayi ve Ticaret Anonim Sirketi

Address: Necip Fazil Bulvari Keyap Carsi Sitesi No: 44 D-1 Blok Dukkan No: 53/2

Umraniye Istanbul 34775 TURKEY

Phone: +90 216 660 0074

Contact Person: Nurettin Eren

Prepared date: March 15, 2026

Device Information

Trade name: Elde Medical Electrodes

Common name: Cutaneous Electrodes

Classification Name: Electrode, Cutaneous (21 CFR 882.1320)

Product Code: GXY

Regulatory Class: Class II

Predicate Device

Trade name: Electrode Pad

Applicant: ShenZhen Deliduo Medical Technology Co.,Ltd.

510(k) Number: K241512

Product Code: GXY

Regulatory Class: Class II

Device Description

The Elde Medical electrode is used as an accessory to the TENS or EMS device unit, which transmits electrical current to patient skin. The electrical current of Elde Medical electrode is first transmitted via the lead wire then transmitted to the conductive gel which is adhered to patient skin.

The Elde Medical electrode is composed of a top cover, lead wire, conductive carbon film, conductive hydrogel media, and a carrier liner. The carrier liner is made of PET (polyethylene terephthalate).

The Elde Medical electrode is non-sterile and intended for single adult patient multiple application use. The Elde Medical electrode has various shapes and sizes.

Indications for Use

The Elde Medical electrode is intended to transmit electrical current to the patient skin for use with transcutaneous electrical stimulation devices. Some common types of the stimulation devices include, but are not limited to TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is for OTC (Over- The -Counter) or Prescription use.

Comparison of Technological Characteristics with the Predicate Device

The following table compares technological and other characteristics of the subject and predicate devices.

	Subject Device Elde Medical Electrode	**Predicate Device (K241512)**	**Comparison**
Trade Name	Elde Medical Electrode	Electrode Pad	N/A
Common Name	Cutaneous electrode	Cutaneous electrode	Same
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
Product Code	GXY	GXY	Same
Regulation Number	21 CFR 882.1320	21 CFR 882.1320	Same
Medical Specialty	Neurology	Neurology	Same
Device Class	II	II	Same
Indications for Use	The Elde Medical electrode is intended to transmit electrical current to the patient skin for use with transcutaneous electrical stimulation devices. Some common types of the stimulation devices include, but are not limited to TENS (Transcutaneous Electrical Nerve Stimulation) and EMS	The Electrode Pad is intended to transmit electrical current to patient skin for use with transcutaneous electrical stimulation devices. Some common types of the stimulation devices include, but are	Same

	(Electrical Muscular Stimulation). The electrode is for OTC (Over-The -Counter) or Prescription use.	not limited to TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is for OTC (Over-The -Counter) or Prescription use	
Target Population	Single patient use and multiple application	Single patient use and multiple application	Same
Prescription Use	OTC and Prescription	OTC and Prescription	Same
Design (Shape & Connection)	Rectangle and square, lead wire with female socket	Electrode Pad: rectangle, square, according to customized specification. Lead wire with female socket, or snap button with male snap connector	Similar
Materials	• Top cover material • Electrically conductive carbon film • Biocompatible conductive hydrogel • Protective film (Electrode carrier liner)	• Top cover material • Electrically conductive carbon film • Biocompatible conductive hydrogel Protective film (Electrode carrier liner)	Same
Electrode Pad Size	Square (50*50mm) Rectangular (50*100mm)	Square (50*50mm) Rectangular (50*100mm)	Same
Patient Contact are of Electrode Pad	Square: 2500 mm^2 Rectangle: 5000mm^2	Square: 2500 mm^2 Rectangle: 5000mm^2	Same
Hydrogel thickness	1.0mm ±0.1mm	0.75mm ±0.15mm	Similar
Electrode Impedance Testing	<300Ω	426-635Ω	Different*1
Conductive carbon film	PU/PE conductive film	PU/PE conductive film	Same
Shelf Life	2 years	2 years	Same
Stainless Steel Adhesion (180° peel)	136 grams minimum (≅1.3N)	136 grams minimum (≅1.3N)	

Biocompatibility	ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-23:2021	ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-23:2021	Same
Sterilization	Non-sterile	Non-sterile	Same
Electrical safety	Lead wire meets clause 8.5.2.3 of IEC 60601-1:2005+AMD1:2012+AMD2:2020	Lead wire meets Clause 8.5.2.3 of AAMI/ANSI ES60601-1: 2005/(R)2012 And A1:2012	Similar

Difference*1 analysis:

The subject device demonstrated impedance values of less than 300 ohms, while the predicate device reported a range of 426–635 ohms. Both devices passed electrical safety and impedance testing, confirming that the difference does not present new or increased risks. The lower impedance of the subject device supports efficient current transfer and does not alter the effectiveness of the electrical stimulation. Differences in reported values may also be attributable to variations in measurement methodology, as the predicate device's test parameters are not specified. In conclusion, the differences in impedance values does not impact the subject device being as safe and effective as the predicate device.

Performance Data (Non-Clinical Tests)

Non-clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device or reference device. The test results demonstrated that the subject 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
- ASTM F1980-21, Standard guide for accelerated aging of sterile barrier systems for medical devices.
- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems
- Peels trength testing(180° stainless steel peel)
- Impedance test per IEC 60601-2-2
- Lead wires test per IEC 60601-1

Clinical Tests

None.

Conclusions

Based on successful biocompatibility testing of subject device, the electrical performance of the insulated lead wire components and Impedance testing, Elde Medical electrodes are safe and effective when used as an interface between a user's skin and an approved nerve and muscle stimulation device. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices identified in the submission. Thus the subject device is substantially equivalent to the predicate devices under K241512.