December 11, 2024

Technomed Europe
Sanne Habets
Team Lead Regulatory Affairs
Amerikalaan 71
Maastricht-Airport, 6199 AE
Netherlands

Re: K241045
Trade/Device Name: Disposable Subdermal Needle Electrode, Corkscrew
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ, IKT
Dated: November 14, 2024
Received: November 14, 2024

Dear Sanne Habets:

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,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine 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)*
K241045

Device Name
Disposable Subdermal Needle Electrode, Corkscrew

Indications for Use *(Describe)*
Needle Electrodes for neurological purposes are intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals, and are intended for stimulation/recording with stimulation/recording equipment for electromyograph (EMG) and nerve potential signals.

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.***

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# K240145
# Traditional 510(k) Summary
# Technomed Europe's Disposable Subdermal Needle Electrode, Corkscrew

***Prepared according to the requirements outlined in 21 CFR 807.92***

## Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared


Technomed Europe
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The Netherlands

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|---|---|
| Phone: | +31 (0) 43 408 6868 |
| Facsimile: | N/A |
| Contact Person: | Sanne Habets, Team Lead Regulatory Affairs |
| E-mail: | regulatory@technomed.nl |


Date Prepared: December 10, 2024

## Trade Name of Device

Disposable Subdermal Needle Electrode, Corkscrew

## Common or Usual Name

Disposable Subdermal Corkscrew Needle Electrode

## Classification

21 C.F.R. § 882.1350, Needle Electrode, Class II, product code GXZ and IKT

## Predicate Devices

**K130136** Disposable Monopolar Needle Electrode and Disposable Subdermal Needle Electrode, 21 C.F.R. § 882.1350, GXZ and IKT.

## Device Description

Disposable Subdermal Needle Electrodes, Corkscrew are single-patient use electrodes, delivered Ethylene Oxide (EtO) sterilized. They include a needle at one end which is connected to a lead wire with a 1.5 mm female safety DIN 42802 connector. The needle, which is fabricated using stainless steel, is formed into a corkscrew shape, with a regular bevel tip. The connecting lead wire, which may be supplied in different lengths and colors is terminated with a DIN 42802 connector to enable connection to recording or monitoring / stimulation equipment.

These devices are used by healthcare professionals specifically trained and certified in electrophysiology techniques, in healthcare facility/hospital environment. These professionals can use the devices on patients for use with recording / monitoring equipment for the recording of biopotential signals including electroencephalography (EEG), electromyography (EMG) and nerve potential signals.

The technological characteristics are described in further detail below.

**Indications for Use**

Needle Electrodes for neurological purposes are intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals, and are intended for stimulation/recording with stimulation/recording equipment for electromyograph (EMG) and nerve potential signals.

**Technological Characteristics**

The DSNE, Corkscrew's technological characteristics remain almost identical to that cleared within K130136.

The proposed modification to the DNSE, Corkscrew is to change the soldering connection between lead wire and needle to a crimped connection, which is glued to the hub. Also, the internal shape of the hub has been optimized to fit the new connection. As demonstrated within this 510(k) premarket notification, this change does not raise new or different questions of safety and effectiveness, and is supported by non-clinical testing of the product.

The positioning, functioning and use of the product remains unchanged.

All other aspects of the device compared to the currently marketed version remain unchanged and are identical. For further information on substantial equivalence, see Table 1.

**Table 1: Substantial Equivalence Summary**

| | Predicate Disposable Subdermal Needle Electrode, Corkscrew (covered by K130136) | New Disposable Subdermal Needle Electrode, Corkscrew | Discussion of potential differences |
|---|---|---|---|
| Device Name | Disposable Subdermal Needle Electrode, Corkscrew | | Identical |
| 510(k) number | K130136 | K241045 | NA |
| 510(k) clearance date | 19th of July, 2013 | Unknown yet | NA |
| Product code | GXZ and IKT | | Identical |
| Intended use / | Needle Electrodes for Neurological purposes are | | Identical |

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| Indications for use (as submitted to FDA during 510(k) submission; and as listed in the IFU) | intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals, and are intended for stimulation/recording with stimulation/recording equipment for electromyograph (EMG) and nerve potential signals. | | |
| Regulation name | Needle Electrode | | Identical |
| Regulation number | 21 CFR 882.1350 | | Identical |
| Target population | All patients | All patients identified by the healthcare professional to benefit from the diagnostic procedures as listed in the indications for use. | Specified in more detail. |
| Where used | Hospital | | Identical |
| Human factors | Predicate and subject device are visually identical, no change in user interface. | | Identical |
| | Compatibility and connections | | |
| Connector | DIN 42802 | | Identical |
| Compatibility | This device is equipped with DIN 42802 connectors and is compatible with any intraoperative neuromonitoring equipment that is equipped with DIN 42802 connections. | | Identical |
| | Dimensions | | |
| Hub diameter | 10 mm | | Identical |
| Hub length | 13 mm | | Identical |
| Needle shape | Spiral (Corkscrew) | | Identical |
| Needle surface area | 49 $mm^2$ | | Identical |
| Needle length (Height of needle windings coming out of the hub) | 2.5-4.0 mm | | Identical |
| Needle diameter | 0.6 mm | | Identical |
| Tip geometry / angle (defining sharpness) | 25° ± 5° (equalling range: 20°-30°) | 24°+2°-4° (equalling range: 20°-26°) | The tip geometry range of the subject device falls within the range of the predicate device, and therefore is equivalent. |
| Lead wire lengths | 1.20-2.5 m | | Identical |
| | Materials | | |
| Needle to lead wire connection | Solder | Brass crimp bushing | Modification, as described in current submission. Non-clinical testing did not raise new or different questions relating to safety and effectiveness. |
| Hub to needle-lead wire | N/A | Glue (Loctite 454) | Modification, as |

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| connection | | | described in current submission. Non-clinical testing did not raise new or different questions relating to safety and effectiveness. |
| Needle | AISI 304 | | Identical |
| Hub | PVC | | Identical |
| Lead wire | Multiple colours PVC insulated tin-plated copper strands | | Identical |
| DIN 42802 connector | PVC over-moulded tin-plated brass | | Identical |
| Protection cap | Polypropylene (PP) | | Identical |
| Electrical insulation | Electrical insulation is present on all surfaces that are not intended to provide electrical contact with the patient. | | Identical |
| | Electrical behaviour | | |
| Impedance | <15 kΩ | | Identical |
| | Mechanical behaviour | | |
| Tensile strength needle to cable | >22N | >25N | Tightened specification. |
| Tensile strength needle to hub | Not specified | >25N | Added specification |
| Maximum retraction force protection cap versus hub (if applicable) | Not applicable | Max. 10N | Addition of protection cap and specification of force. This did not raise new or different questions relating to safety and effectiveness. |
| Torsion force Needle to hub | Not specified | > 15.5 Ncm | Added specification |
| | Other information | | |
| Lead wire type | Single / Twisted | | Identical |
| Hub material colour | Blue | | Identical |
| Single use | Yes | | Identical |
| Provided to the user sterile | Yes | | Identical |
| Sterilization method | Ethylene oxide | | Identical |
| Sterility assurance level | $10^{-6}$ | | Identical |
| Shelf life | 3 years | | Identical |
| Sterile barrier / container (transparent - film) | Biaxially oriented polyethylene film | | Identical |
| Sterile barrier / container (paper) | Gas Paper | | Identical |
| Pouch size | 175x75 mm<br>200x100 mm | | Identical |
| Number of items per box | 12 pairs or 24 single pieces | | Identical |
| Anatomical site | To be applied to subdermal tissue | | Identical |
| Energy used and/or delivered | No energy used, no energy delivered, only conduction of electrical signals | | Identical |

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|---|---|---|---|
| Biocompatible | Yes | Yes, tested in accordance with current ISO 10993 series | Non-clinical testing did not raise new or different questions relating to safety and effectiveness. |

**Non-clinical Testing**

Non-clinical testing was conducted to validate the performance and safety of the subject device, to ensure that the device performs as intended and meets the design specifications.

Mechanical, dimensional, electrical, and visual aspects of the device were tested according to internal test method.

Regarding accelerated aging, aging was performed according to ASTM F1980-21. Mechanical, dimensional, electrical, and visual assessment were performed according to internal test method. Label assessment was performed according to ISO 20417 (Ed. 1). Pouch integrity testing was performed according to ASTM F1929-15.

A transit simulation was performed according to ISTA 3A (2018 edition). Electrical and mechanical assessment of the products was done according to internal test methods.

Biocompatibility testing was performed by an external laboratory according to the ISO 10993 series. This included chemical characterization, cytotoxicity, intracutaneous reactivity, acute systemic toxicity, sensitization and pyrogenicity testing.

Regarding Electrical, Mechanical and Thermal Safety testing, compliance with the applicable section of IEC 60601-1 (Ed. 3.2) was tested.

Sterilization validation (ISO 11135:2014 (Ed. 2))) was leveraged from the predicate device as the changes to the product do not affect the sterilization validation, nor result in the need for choosing a different worst-case product in sterilization revalidation. The reason is that device and packaging materials, device dimensions and device shape are substantially equivalent to the predicate.

Regarding usability (IEC 62366-1:2015 (Ed. 1.1)), the User Interface of Unknown Provenance principle was applied in accordance with Annex C of IEC 62366-1 as the User Interface has been commercialized prior to the release of the standard and no modifications to the User Interface or its parts have been made.

A summary of the non-clinical testing performed on the subject device, Disposable Subdermal Needle Electrodes, Corkscrew is provided in **Table 2**.

**Table 2: Summary of Non-Clinical Testing**

| Test | Method | Results / Comment |
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| Performance Testing (Visual, dimensional, electrical, and mechanical aspects) | Internal test methods were applied.<br>• Visual checks: including fixation of protection cap to hub, visibility of bare wires, visual damage.<br>• Dimensional checks<br>• Electrical testing: including impedance measurements.<br>• Mechanical testing: including torsion and pull force measurements. | The product passed the tests and meets the set requirements.<br><br>The testing did not raise new or different questions of safety and effectiveness. |
| Shelf life (Accelerated aging) | Aging was performed according to ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.<br>FDA recognition number: 14-575<br><br>Mechanical, dimensional, electrical, and visual assessment was performed according to internal test method.<br><br>Label assessment method was based on ISO 20417:2021 (Ed. 1) Medical devices – Information to be supplied by the manufacturer.<br>FDA recognition number: 5-135<br><br>Pouch integrity testing was performed according to ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.<br>FDA recognition number: 14-484 | The product passed the 3-years accelerated shelf-life validation and meets the set requirements.<br><br>The testing did not raise new or different questions of safety and effectiveness. |
| Transit testing | Transit simulation was performed according to ISTA 3A (2018) Packaged-Products For Parcel Delivery System Shipment 70 Kg (150 Lb) Or Less.<br>FDA recognition number: 5-126<br><br>Electrical and mechanical assessment were performed according to internal test method.<br><br>Label assessment method was based on ISO 20417:2021 (Ed. 1) Medical devices – Information to be supplied by the manufacturer.<br>FDA recognition number: 5-135<br><br>Pouch integrity testing was performed according to ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.<br>FDA recognition number: 14-484 | The product passed the tests and meets the set requirements.<br><br>The testing did not raise new or different questions of safety and effectiveness. |

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| Electrical, Mechanical and Thermal Safety | IEC 60601-1:2005+AMD1:2012 +AMD2:2020 (Ed. 3.2) – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance; section 8.5.2.3.<br>FDA recognition number: 19-49 | The product meets the applicable requirements of section 8.5.2.3.<br><br>The testing did not raise new or different questions of safety and effectiveness. |
| Biocompatibility (including Chemical characterization, cytotoxicity, intracutaneous reactivity, acute systemic toxicity, sensitization and pyrogenicity) | A biological evaluation plan was written. Chemical characterization, cytotoxicity, intracutaneous reactivity, acute systemic toxicity, sensitization and pyrogenicity were tested in accordance with the below listed standards by an independent laboratory. Based on the data, a biological risk assessment was written.<br>• ISO 10993-1:2018 (Ed. 5) - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.<br>FDA recognition number: 2-258<br>• ISO 10993-7:2008 (Ed. 2) - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.<br>FDA recognition number: 2-275<br>• ISO 10993-18:2020 (Ed. 2) - Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process<br>FDA recognition number: 2-276<br>• ISO 10993-5:2009 (Ed. 3) - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity<br>FDA recognition number: 2-245<br>• ISO 10993-10:2021 (Ed. 4) - Biological evaluation of medical devices - Part 10: Tests for skin sensitization<br>FDA recognition number: 2-296<br>• ISO 10993-23:2021 (Ed. 1) - Biological evaluation of medical devices - Part 23: Tests for irritation<br>FDA recognition number: 2-291<br>• ISO 10993-11:2017 (Ed. 3) - Biological evaluation of medical devices -<br>Part 11: Tests for systemic toxicity<br>FDA recognition number: 2-255<br>• ISO 10993-6:2016 (Ed. 3) - Biological evaluation of medical devices - Part 6: Tests for local effects after implantation | The product is evaluated to be biocompatible.<br><br>The testing did not raise new or different questions of safety and effectiveness. |

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| | FDA recognition number: 2-247<br>• ISO 10993-3:2014 (Ed. 3) - Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity<br>FDA recognition number: 2-228 | |
| Sterilization | ISO 11135:2014+AMD1:2018 (Ed. 2) – Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices.<br>FDA recognition number: 14-529<br><br>The sterilization revalidation as executed in 2022 is still valid for the device that is subject of this submission as the predicate device was already part of the product portfolio that was validated in 2022; and the changes to the product do not affect the sterilization validation, nor result in the need for choosing a different worst-case product in sterilization revalidation. The reason is that device and packaging materials, device dimensions and device shape are substantially equivalent to the predicate. | The changes to the product do not have any impact on the latest sterilization validation.<br><br>The changes to the product did not raise new or different questions of safety and effectiveness regarding sterilization. |
| Pyrogenicity | A LAL test of the product was performed after sterilization by the sterilization provider. | The product conformed to the requirements of the test.<br><br>The changes to the product did not raise new or different questions of safety and effectiveness. |
| Usability | IEC 62366-1:2015+AMD1:2020 (Ed. 1.1) – Medical devices – Part 1: Application of usability engineering to medical devices.<br>FDA recognition number: 5-129<br><br>The user interface of unknown provenance (UOUP) principle was applied. The user interface for both the predicate device and the subject device are equivalent. | The UOUP assessment of the DSNE, Corkscrew determined the usability of the DSNE, Corkscrew to be acceptable.<br><br>The changes to the product did not raise new or different questions of safety and effectiveness regarding usability. |

**Clinical testing**

There is no clinical testing required to support this submission.

**Substantial Equivalence**

The device and its predicate are equivalent in most aspects, such as product classification, connections, sizes, majority of the materials used, sterilization characteristics, packaging materials, and safety characteristics. The difference is the internal joining method of the needle to the lead wire. The predicate device utilizes a soldering connection, whereas the

proposed subject device utilizes a brass crimped connection, which is glued to the hub. Also, the internal shape of the hub has been optimized to fit the new connection.

The change does not raise new or different questions of safety and effectiveness and is supported by non-clinical testing of the product.

Thus, in summary, the DSNE, Corkscrew as cleared under K130136 and as part of the current submission are considered equivalent and do not raise new or different questions of safety and effectiveness.

All other aspects of the device compared to the predicate device remain unchanged and are identical. For further information on substantial equivalence, see Table 1.

**Conclusion**

In summary, the intended use, and indications for use for the DNSE, Corkscrew and its predicate devices are identical.

Non-clinical testing performed on the DSNE, Corkscrew has demonstrated that the minor modifications to Disposable Subdermal Needle Electrode, Corkscrew do not raise new or different questions regarding safety and effectiveness.

Although the internal joining method of needle to lead wire and the internal shape of the hub change, the overall operating principles of the device remain the same.

Thus, the information and data provided in this 510(k) premarket notification submission support a finding of substantial equivalence for the DNSE, Corkscrew.

A tabular comparison of device characteristics can be found in Table 1.