March 15, 2026

Technomed Europe
Alan Yik
Senior Regulatory Affairs Specialist
Wiebachstraat 25a
Kerkrade, 6466 NG
Netherlands

Re: K253581
Trade/Device Name: Disposable Concentric Needle Electrode 0.30x25mm Red (TE/B50700-001);
Disposable Concentric Needle Electrode 0.40x25mm Yellow (TE/B50700-002);
Disposable Concentric Needle Electrode 0.30x30mm Pink (TE/B50700-006);
Disposable Concentric Needle Electrode 0.45x37mm Green (TE/B50700-003);
Disposable Concentric Needle Electrode 0.45x50mm Blue (TE/B50700-004);
Disposable Concentric Needle Electrode 0.60x75mm Violet (TE/B50700-005)
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic Electromyograph Needle Electrode
Regulatory Class: Class II
Product Code: IKT, GXZ
Dated: November 17, 2025
Received: November 17, 2025

Dear Alan Yik:

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,

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

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.	K253581

Please provide the device trade name(s).

Disposable Concentric Needle Electrode 0.30x25mm Red (TE/B50700-001);
Disposable Concentric Needle Electrode 0.40x25mm Yellow (TE/B50700-002);
Disposable Concentric Needle Electrode 0.30x30mm Pink (TE/B50700-006);
Disposable Concentric Needle Electrode 0.45x37mm Green (TE/B50700-003);
Disposable Concentric Needle Electrode 0.45x50mm Blue (TE/B50700-004);
Disposable Concentric Needle Electrode 0.60x75mm Violet (TE/B50700-005)

Please provide your Indications for Use below.

Disposable Concentric Needle Electrodes are intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyography (EMG) and nerve potential signal.

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)

Disposable Concentric Needle Electrode (DCNE) 510(k)

510(k) Summary
K253581

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

Technomed Europe
Wiebachstraat 25a, Kerkrade, 6466 NG, Netherlands

Phone: +44 (0) 1994 240798
Contact Person: Alan Yik, Senior Regulatory Affairs Specialist (ayik@welcony.com)
Date Prepared: 22nd Jan 2026

B. Device Name

Device Trade Name	Disposable Concentric Needle Electrode 0.30x25mm Red (TE/B50700-001); Disposable Concentric Needle Electrode 0.40x25mm Yellow (TE/B50700-002); Disposable Concentric Needle Electrode 0.30x30mm Pink (TE/B50700-006); Disposable Concentric Needle Electrode 0.45x37mm Green (TE/B50700-003); Disposable Concentric Needle Electrode 0.45x50mm Blue (TE/B50700-004); Disposable Concentric Needle Electrode 0.60x75mm Violet (TE/B50700-005)
Common Name	Needle Electrode
Classification Name	Electrode, Needle
Regulation Number	890.1385
Product Code(s)	IKT, GXZ

C. Legally Marketed Predicate Devices

Primary Predicate Device:
Technomed EEG / EMG needle electrodes (K990015)
Product Code: 21 CFR § 882.1350 GXZ

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Disposable Concentric Needle Electrode (DCNE) 510(k)

Reference Devices

1. Disposable hypodermic EMG needle electrode (K062437)
   Product Code: 21 CFR § 890.1385 IKT

2. Disposable Monopolar and Subdermal Needle Electrodes (K130136)
   Product Code: 21 CFR § 890.1385 IKT
   Subsequent Product Code21 CFR § 882.1350 GXZ
   Product Code: 21 CFR § 890.1385 IKT

D. Device Description Summary

The Disposable Concentric Needle Electrode (DCNE) is a recording electrode used for recording of bio-electric, electromyography (EMG) or electroencephalography (EEG) signals in patients undergoing clinical neurophysiological testing. It is inserted into muscle tissue of patient, acting as an interface between the EMG equipment and the patient. It is connected to the EMG cable (not in this submission), which is connected to the EMG equipment to detect bio-electric signals distally.

The subject devices are invasive, single-use and supplied sterile. It is used by healthcare professionals, specifically trained and certified in electrophysiology and recording/monitoring techniques.

The subject devices consist of 6 variants. The differences between the variants are the diameter, length of the needle and the color of the handle.

E. Intended Use/ Indications for Use

Disposable Concentric Needle Electrodes are intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalography (EEG), electromyography (EMG) and nerve potential signal.

F. Technological Comparison

Technological Characteristics

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Disposable Concentric Needle Electrode (DCNE) 510(k)

Technologically the subject device DCNE is identical to the predicate devices as covered by K990015. Modifications have been made to the joining method from needle to the connector cage, changing from a soldering connection between needle and connector cage to a crimped connection which is glued to the hub. This hub also has a different inner shape compared to the predicate device. Also, the plating finish of the brass connector (Tin vs gold (predicate device) and the core wire material are changed from stainless steel to tungsten to achieve a better performance. Finally, the tip geometry has been modified by adjusting the grinding angles to improve puncturing and sliding behavior. As demonstrated by the non-clinical testing submitted with this submission, the proposed modification does not raise new or different questions of safety or effectiveness. Non-clinical test was performed and attached in this submission.

The basic design of the subject device DCNE in this submission is very similar to the design of the predicate device as covered by K990015. Both devices are the interface between the diagnostic or monitoring device and the patient. They transmit electrical signals from the human body to the monitoring device.

Whilst the joining method of the needle to the connector cage, the core wire material, finished plating of the connector, tip geometry and internal shape of the hub are different, the functionality of the product to transmit electrical signals in both the predicate and the subject device is unchanged. The same crimping system is used in the reference device DHNE which its functionality is proven to be safe and effective in the previous submission K062437. Refer to Attachment 3.07.a - Transit and Aging Rationale for the detail comparison. In addition, there is new materials used in the subject devices which has been proven safe by compare with the reference device DMNE cleared under K130136. Refer to Attachment 3.05.06 – Biocompatibility for detail for the demonstration of biocompatibility of subject device.

To evaluate the difference between the two products, detailed information can be found in the Substantial Equivalence Summary Table (See Table 1).

In summary, the following can be concluded:

- Compatibility and connections: Both the predicate and subject device can be connected to a reusable cable connected with a 5-pole DIN connector; and therefore, are compatible with any intraoperative neuromonitoring equipment that is equipped with 5-pole DIN connector.
- Sizes: Hub diameter and length, Needle length and diameter are identical
- Tip geometry: The tip geometry is change due to a change in the grinding angles to improve puncturing and sliding behavior

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Disposable Concentric Needle Electrode (DCNE) 510(k)

- Materials: Materials used in the product are identical for the outside needle and the hub. The differences are the internal joining method of the needle to the connector cage, changing from solder to crimp bushing with glue; the connector plating, which does not have patient contact; and the core wire material, which has changed from stainless steel to tungsten.
- Other information: sterility and sterilization, shelf life and packaging are identical for the predicate and subject device.

For the predicate device, tensile strengths between needle and hub were not specified in the original submission (K990015), however have been compared in the non-clinical performance testing. Both the predicate device and the device that is subject of this submission conform to the set specifications and testing requirements.

Thus, the subject device DCNE is substantial equivalence to the predicate devices in terms of the technological principles.

Principles of Operations

The subject device Disposable Concentric Needle Electrodes (DCNE) has the same principles of operation as with the predicate device cleared under K990015. Both the subject and predicate devices need to be inserted into muscle tissue. They are the interface between the EMG equipment and the patient. They transmit signals from the human body to the EMG equipment. These signals are extremely weak. Therefore, amplification and elimination of unwanted noise is essential. Since the human body acts like a radio antenna, it is picking up interference from broadcast radio transmissions or even from the lighting and electrical wiring in the laboratory. Special amplifiers, called differential amplifiers, are used to help eliminate the unwanted interference signals and to provide the high gain necessary (up to 1V) before the signal can be adequately recorded. This is usually obtained from a surface electrode on a body part away from the muscle under investigation, and away from any contracting musculature (especially the heart), i.e., a so-called reference electrode. This electrode will pick up the unwanted interference signal. The differential amplifier operates by subtracting the reference signal from the EMG / EEG electrode signal. This leaves only the small EMG / EEG signal, which goes on to be amplified. Unwanted noise is thus eliminated.

The cannula of the Disposable Concentric Needle Electrode, located at the tip of the needle, acts as its reference electrode. Its active core acts as its active electrode. The active core is embedded in an insulating material to electrically insulate the two electrodes from each other.

Both the subject devices and the predicate devices have the following advantages:

- Precision: Allows for targeted muscle activity recording.

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Disposable Concentric Needle Electrode (DCNE) 510(k)

- Safety: Disposable design reduces the risk of infection.
- Minimal Invasiveness: The needle is small and sharp, causing minimal discomfort.

In conclusion, the principles of operation for the subject device and the predicate device are identical.

G. Non-Clinical and/or Clinical Test Summary & Conclusions

Performance testing of the Disposable Concentric Needle Electrode (DCNE) demonstrates that the device performs as intended for and is therefore substantially equivalent to the primary predicate device. The following nonclinical testing within this submission is relied upon for a determination of substantial equivalence:

Visual inspection
The visual inspection was carried out using a microscope (20x magnification) to examine the integrity of subject devices, ensuring that the needle is not damaged, and the needle tip is free of burr and is not blunt. Additionally, the alignment of the indicator of the hub, the color of the hub, and the recording area of the needle tip was verified. Furthermore, the back side connector was inspected to be clean and not damaged. The straightness of the needle, the length and diameter of the needle were also verified.

Puncture test
The puncture test was executed on needles using the tensile testing machine. The needle was fixed in the upper compartment of the tensile testing machine, and the PU foil (simulating the skin) is placed in the lower compartment, on a holder that features a 10mm diameter circle area where the PU foil is exposed. The puncture test is executed at a constant velocity established at 50mm/min. The tested needle was inserted into the PU foil for a puncture depth of 15mm.

During this test, the puncture force and the friction force values were examined and reported. The puncture force represents the force at the end of the cutting phase, while the friction force represents the force exerted by sliding the cannula through the PU foil.

Impedance
The electrical test was performed on needles, where the LCR meter is used to measure the capacitance (C, [nF]), and the resistance (R, [kΩ]) of the subject devices. The tested needle was placed in a container with physiological solution (0.9% NaCl). The measured capacitance and resistance values were examined and reported.

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Disposable Concentric Needle Electrode (DCNE) 510(k)

Push test needle to connector

This test measured the connection between the hub and the connector by doing a mechanical push test using the tensile testing machine. The pushing force was measured and recorded.

Pull test needle to connector

This test measured the connection between the needle and the connector by doing a mechanical pull test using the tensile testing machine. The pull force was measured and recorded.

Biocompatibility

Biological tests were conducted to demonstrate the subject devices are biologically safe. According to the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation medical devices - Part 1: Evaluation and testing within a risk management process", the test conducted including

- Physical and chemical characterization
- Cytotoxicity testing
- Toxicological evaluation
- Sensitization testing
- Intracutaneous reactivity testing
- Acute systemic toxicity testing

Clinical Testing - Not Applicable

H. Conclusion

Based on the above testing and analysis of performance data – it can be concluded that the subject device Disposable Concentric Needle Electrode is substantially equivalent to the primary predicate device cleared under K990015. Refer to Attachment 3.08 Bench Testing for the details of the bench testing.

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I. Predicate Performance Comparison Table / Reference Device

Table 1: Substantial Equivalence / reference Summary

Criteria	Disposable Concentric Needle Electrode (Subject Device in this submission)	Technomed Europe diagnostic needle electrodes (Primary Predicate)	DISPOSABLE HYPODERMIC EMG NEEDLE ELECTRODE (Reference Device)	Disposable Monopolar Needle Electrode (Reference Device)	Evaluation of Differences
Manufacturer	Technomed Europe	Technomed Europe	Technomed Europe	Technomed Europe	N/A
Device Name	Disposable Concentric Needle Electrode	Disposable Concentric Needle Electrode	Disposable Hypodermic Needle Electrode	Disposable Monopolar Needle Electrode	N/A
510(k) number	/	K990015	K062437	K130136	N/A
Product code	IKT and GXZ	IKT and GXZ	IKT	IKT and GXZ	Identical to the primary predicate device
Intended use / Indications for use	Disposable Concentric Needle Electrodes are intended for use with recording, monitoring equipment for the recording of biopotential signals including electroencephalography (EEG), electromyography (EMG) and nerve potential signal.	Technomed Europe diagnostic needle electrodes are intended to be inserted in the subdermal, muscle or nerve tissue to sense bio-electric, EMG or EEG signals distally, and are intended to be proximal connected to electromyography / electroencephalogram recording equipment.	Disposable Hypodermic Needle Electrodes are intended for use in muscle stimulation and monitoring, motor unit action potential recording, and drug delivery. The only drug that may be used with this device is Botox Type A./ The Disposable Hypodermic Needle Electrodes are used for EMG recording and stimulation in patients undergoing clinical neurophysiological testing combined with delivery of injectable drugs (Botox Type A).	Disposable Monopolar Needle Electrodes are intended for use with recording and monitoring equipment for the recording of biopotential signals including electroencephalography (EEG), electromyography (EMG) and nerve potential signals, and are intended for stimulation and recording with stimulation / recording equipment for electromyography (EMG) and nerve potential signals.	Substantial equivalent to the predicate device, as described in current submission
Regulation name	Diagnostic electromyograph needle electrode	Diagnostic electromyograph needle electrode	Electrode, Needle, Diagnostic Electromyograph	Electrode, Needle	Identical to the primary predicate device
Regulation number	21 CFR 890.1385	21 CFR 890.1385	21 CFR 890.1385	21 CFR 882.1350	Identical to the primary predicate device
Target population	The intended patients benefiting from the use of these devices are any patients identified by the medical experts to benefit from such diagnostic procedure.	The intended patients benefiting from the use of these devices are any patients identified by the medical experts to benefit from such diagnostic procedure.	The intended patients benefiting from the use of these devices are any patients identified by the medical experts to benefit from such diagnostic procedures	The intended patients benefiting from the use of these devices are any patients identified by the medical experts to benefit from such diagnostic procedures	Identical to the primary predicate device

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Criteria	Disposable Concentric Needle Electrode (Subject Device in this submission)	Technomed Europe diagnostic needle electrodes (Primary Predicate)	DISPOSABLE HYPODERMIC EMG NEEDLE ELECTRODE (Reference Device)	Disposable Monopolar Needle Electrode (Reference Device)	Evaluation of Differences
Where used	The Disposable Concentric Needle Electrodes are used in highly controlled environments, according to facility specific procedures aligned with local, national and/or international guidance	The Disposable Concentric Needle Electrodes are used in highly controlled environments, according to facility specific procedures aligned with local, national and/or international guidance	The Disposable Hypodermic Needle Electrodes are used in highly controlled environments, according to facility specific procedures aligned with local, national and/or international guidance	The Disposable Monopolar Needle Electrodes are used in highly controlled environments, according to facility-specific procedures aligned with local, national and / or international guidance	Identical to the primary predicate device
Dimensions					
Hub diameter	8 mm	8 mm	7.78 mm (luer lock)	8 mm	Identical to the primary predicate device
Hub length	20 mm	20 mm	20 mm	20 mm	Identical to the primary predicate device
Needle shape	Straight	Straight	Straight	Straight	Identical to the primary predicate device
Needle surface area	Recording area 0.03 or 0.07 mm^2 depending on needle size	Recording area 0.03 or 0.09 mm^2 depending on needle size	Recording/ Stimulation area 0.06 mm^2 0.10 mm^2 0.12 mm^2 0.15 mm^2 0.26 mm^2	Recording/ Stimulation area ø 0.35mm/ ø 0.45mm 0.48mm^2/ 0.78mm^2	Substantial equivalent to the predicate device, as described in current submission. Non-clinical testing did not raise new or different questions relating to safety and effectiveness
Needle length (Height of needle windings coming out of the hub)	25mm 37mm 50mm 75mm	25mm 37mm 50mm 75mm	25mm 37mm 50mm 75mm	25mm 37mm 50mm 75mm	Identical to the primary predicate device
Needle diameter	0.30mm 0.40mm 0.45mm 0.60mm	0.30mm 0.40mm 0.45mm 0.60mm	0.30mm 0.40mm 0.45mm 0.50mm 0.70mm	0.35mm 0.45mm	Identical to the primary predicate device
Tip geometry / angle (defining sharpness)	Trocar/ 15°	Trocar/ 12°	Trocar (pencil)/ 9°	Trocar	Substantial equivalent to the predicate device, as described in current submission. Non-clinical testing did not raise new or different questions relating to safety and effectiveness
Materials of Construction					

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Criteria	Disposable Concentric Needle Electrode (Subject Device in this submission)	Technomed Europe diagnostic needle electrodes (Primary Predicate)	DISPOSABLE HYPODERMIC EMG NEEDLE ELECTRODE (Reference Device)	Disposable Monopolar Needle Electrode (Reference Device)	Evaluation of Differences
Hub to needle connection	Crimping + Glue	Solder	Brass (crimp connection lead wire -needle)	Solder	Equivalent connection with the reference device Substantial equivalent to the predicate device. as described in current submission, Non-clinical testing did not raise new or different questions relating to safety and effectiveness
Core wire	Stainless Steel AISI304	Tungsten	N/A	N/A	Substantial equivalent to the predicate device, as described in current submission. Non-clinical testing did not raise new or different questions relating to safety and effectiveness
Cannular	Stainless Steel AISI304	Stainless Steel AISI304	Stainless Steel AISI304	Stainless Steel AISI304	Identical to the primary predicate device
Connector cage	Tin plated brass	Gold plated brass	N/A (lead wire)	Tin plated brass	Substantial equivalent to the predicate device, as described in current submission. Non-clinical testing did not raise new or different questions relating to safety and effectiveness
Hub	Polyamide PA6	Polyamide PA6	Polyamide, food grade	Polyamide PA6	Identical to the primary predicate device
Protecting tube	Low-density polyethylene	Low-density polyethylene	polyethylene	Low-density polyethylene	Identical to the primary predicate device
Isolation core wire	Polyesterimide	Polyesterimide	N/A	N/A	Modification, as described in current submission. Non-clinical testing did not raise new or different questions relating to safety and effectiveness
Lubrication	Non curable Silicone	Non curable Silicone	N/A	Silicone mixture 20% MF 360	Identical to the primary predicate device

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Criteria	Disposable Concentric Needle Electrode (Subject Device in this submission)	Technomed Europe diagnostic needle electrodes (Primary Predicate)	DISPOSABLE HYPODERMIC EMG NEEDLE ELECTRODE (Reference Device)	Disposable Monopolar Needle Electrode (Reference Device)	Evaluation of Differences
Performance					
Impedance	Resistance ≤ 20 kΩ Capacitance ≥ 3.5 nF	Resistance ≤ 20 kΩ Capacitance ≥ 3.5 nF	Impedance < 100 k Ω	Impedance < 200 k Ω	Identical to the primary predicate device
Tensile strength needle to hub	0.30mm: > 11N 0.40mm: > 22N 0.45mm: > 22N 0.60mm: > 34N	0.30mm: > 11N 0.40mm: > 22N 0.45mm: > 22N 0.60mm: > 34N	0.30mm: > 11N 0.40mm: > 22N 0.45mm: > 22N 0.50mm: > 22N 0.70mm: > 40N	0.30mm: > 11N 0.45mm: > 22N	Identical to the primary predicate device
Connector cage to Hub Compression	> 3N	> 3N	Tensile strength > 25N (cable to connector)	> 3N	Identical to the primary predicate device
Energy used and/or delivered	No energy used, no energy delivered, only conduction of electrical signals	No energy used, no energy delivered, only conduction of electrical signals	Used conduction of electrical signals (recording & stimulation)	Used conduction of electrical signals (recording & stimulation)	Identical to the primary predicate device
Packaging					
Single use	Yes	Yes	Yes	Yes	Identical to the primary predicate device and reference devices
Supplied as sterile	Yes	Yes	Yes	Yes	Identical to primary predicate and reference devices
Sterilization method	Ethylene oxide	Ethylene oxide	Ethylene oxide	Ethylene oxide	Identical to primary predicate and reference devices
Sterility assurance level (SAL)	10^{-6}	10^{-6}	10^{-6}	10^{-6}	Identical to primary predicate and reference devices
Shelf life	Three years	Three years	Three years	Three years	Identical to primary predicate and reference device
Sterile barrier / container (transparent - film)	Film PET/PE	Film PET/PE	Film PET/PE	Film PET/PE	Identical to primary predicate and reference devices
Sterile barrier / container (paper)	Medical paper	Medical paper	Medical paper	Medical paper	Identical to primary predicate and reference devices
Pouch size	50 x 200 mm (with thumbhole)	50 x 200 mm (with or without thumbhole)	100 x 200 (with or without thumbhole)	50 x 200 mm (with thumbhole)	Identical to the primary predicate device

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Vat-nr.: NL803379936B01

Criteria	Disposable Concentric Needle Electrode (Subject Device in this submission)	Technomed Europe diagnostic needle electrodes (Primary Predicate)	DISPOSABLE HYPODERMIC EMG NEEDLE ELECTRODE (Reference Device)	Disposable Monopolar Needle Electrode (Reference Device)	Evaluation of Differences
Packaging Shelf box	200 x 140 x 50mm	200 x 140 x 50 mm	200 x 140 x 50 mm	200 x 140 x 50mm	Identical to primary predicate and reference devices
Number of items per Shelf box	25	25	10	25	Identical to the primary predicate device
Packaging Shipping carton	48 shelf boxes per Shipping carton	48 shelf boxes per Shipping carton	48 shelf boxes per Shipping carton	48 shelf boxes per Shipping carton	Identical to primary predicate and reference devices

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