K130136

**510(k) Summary**

JUL 19 2013

| | |
|---|---|
| Manufacturer: | Technomed Europe<br>Amerikalaan 71<br>6199 AE Maastricht Airport<br>The Netherlands |
| Submitted by: | Technomed Europe<br>Amerikalaan 71<br>6199 AE Maastricht Airport<br>The Netherlands<br>Tel.: (+31) 43-408 6868<br>Fax: (+31) 43-408 6888 |
| Contact person: | Mr. Pierre Vreuls<br>Manager Regulatory Affairs and Quality Assurance<br>E-mail: pvreuls@technomed.nl |
| Date: | June 6, 2013 |
| Proprietary Name: | Disposable Monopolar and Subdermal Needle Electrodes |
| Common/usual Name: | Needle Electrode |
| Classification Name: | Needle electrodes are classified as class II per 21 CFR section 882.1350 product code GXZ and section 890.1385 product code IKT (diagnostic electromyograph needle electrode). |
| Legally Marketed Predicate Devices: | K990015: Technomed Europe Needle Electrodes<br><br>K050325: Technomed Europe Disposable Concentric Probe, Disposable Bipolar Probe, Disposable Monopolar Probe<br><br>K062437: Technomed Europe Disposable Hypodermic EMG Needle Electrode<br><br>K112034: Carefusion 209, Inc. TECA™ ELITE Disposable Concentric Needles<br><br>K072276: Xian Friendship Electronics Co., Ltd., Subdermal Needle Electrodes |
| Device description: | Needle Electrodes are passive devices used for recording, monitoring and stimulation during EEG, EMG, nerve conducting studies and IONM. The Needle Electrodes have |

different tip shapes for performing different recording and stimulating procedures.

The Needle Electrodes are disposable and designed for single use and are labeled accordingly. The disposable Needle Electrodes are delivered sterile and can be used after opening of the sterile package.

The needles are comprised of a stainless steel or platinum alloy needle, electrically connected to a lead wire, or with a connector for connection to a separate lead wire. Monopolar needles are coated with a polytetrafluoroethylene coating. In case of a pre-connected lead wire the other end is a regular industry standard DIN 42802 safety connector.

The needles are invasive as they are used subcutaneously. Positioning and use is under supervision of a licensed physician.

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

Comparison to predicates:

| **Characteristic** | **Predicate device disposable needle electrode EEG / EMG [K990015]** | **Predicate device Subdermal Needle Electrodes[K072276]** | **Predicate device disposable concentric needles [K112034]** | **Disposable monopolar and subdermal needle electrodes[K130136]** |
|---|---|---|---|---|
| Name | Technomed EEG / EMG needle electrodes | Xian Friendship Subdermal Needle Electrodes | Carefusion 209, Inc. TECA™ ELITE Disposable Concentric Needles | Disposable monopolar needle electrode, Disposable subdermal needle electrode |
| Device class | Class II | Class II | Class II | Same |
| Product code | IKT and GXZ | GXZ | IKT | IKT and GXZ |
| Device type | Disposable needle electrode | Disposable subdermal needle electrode | Disposable concentric needle | Disposable monopolar needle electrode, Disposable subdermal needle electrode |

| | | | | |
|---|---|---|---|---|
| Indications for use | Technomed Europe diagnostic needle electrodes are intended to be inserted in the subdermal muscle or nerve tissue only to sense bio-electric. EMG or EEG. signals distally. and will proximal be connected to: Electromyography/elec troencephalogram recording equipment | Subdermal Needle Electrodes are intended for use with recording. monitoring and stimulation/recording equipment for the recording of biopotential signals. including electroencephalograph (EEG). electromyograph (EMG) and nervepotential signals and for stimulation during the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The electrodes are sterile and for single patient use only. | Disposable Concentric Needles are intended for use with recording. monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals Including electromyography (EMG) and nerve potential signals. | Disposable Monopolar and Subdermal Needles are intended for use with recording. monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals Including electromyography (EMG) and nerve potential signals. |
| Target population | All patients | All patients | All patients | Same |
| Anatomical sites | Peripheral nerves and muscles | Peripheral nerves and muscles | Peripheral nerves and muscles | Same |
| Where used | Hospital | Hospital | Hospital | Same |
| Device design<br>• Diameters<br>• Lengths<br><br>• Tip geometry | Diameters: 0.30mm to 0.60mm<br>Lengths:25 to 75mm (monopolar). 13 mm (straight subdermal)<br><br>Tip geometry: front bevel and pencil tip | Diameter: 0.4mm and 0.6mm<br>Length: 13mm (subdermal) and 23mm (corkscrew)<br><br>Tip geometry: front bevel | Diameters: 0.30mm to 0.60mm<br>Lengths: 25mm to 75mm<br><br>Tip geometry: back bevel | Diameters: 0.30mm to 0.60mm<br>Lengths: 25 to 75mm (monopolar). 7 to 20 mm (subdermal). 23 mm (corkscrew)<br>Tip geometry: front bevel and pencil tip |
| Recording / stimulation area | $0.42mm^2 - 44.5mm^2$ | $16.3mm^2 - 44.5\ mm^2$ | $0.025mm^2 - 0.068mm^2$ | Same as K990015 |
| Electrode materials | Stainless steel | Stainless steel | Stainless steel. Pt/Ir or W | Stainless steel. Pt/Ir |
| Coatings | PTFE | n/a | Polyesterimide and low friction lubricant | Same as K990015 |
| Cables | PVC insulated tin plated copper lead wire | PVC insulated tin plated copper lead wire | Detachable reusable cable | Same as K990015 |
| Connectors | DIN 42802 1.5mm touch proof | DIN 42802 Touch proof connector | 5 pole DIN | Same as K990015 and K072276 |
| Electrical insulation | Electrical insulation on all surfaces not intended to provide electrical contact with the patient and connection | Electrical insulation on all surfaces not intended to provide electrical contact with the patient and connection | Electrical insulation on all surfaces not intended to provide electrical contact with the patient and connection | Same |
| Impedance | <200kΩ | Unknown | <300kΩ | Same as K990015 |

| | | | | |
|---|---|---|---|---|
| Sterilization method | EO ethylene oxide | EO ethylene oxide | EO ethylene oxide | EO ethylene oxide |
| Sterility assurance level (SAL) | $10^{-6}$ | Unknown | $10^{-6}$ | Same as K990015 |
| Manufacturers | Technomed Europe | Xian Friendship | CareFusion | Technomed Europe |

Biocompatibility: The stainless steel monopolar needle with the polytetrafluoroethylene coating is identical to the Technomed Europe disposable hypodermic needles (K062437) in formulation, processing, sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents). No further biocompatibility testing with the final finished device was determined to be necessary.

The stainless steel or the platinum/iridium material used in the subdermal needle is identical to that of the Technomed Europe needle electrodes (K990015). No further biocompatibility testing with the final finished device was determined to be necessary.

Performance testing: Electrical safety and compatibility was verified, including impedance testing. Sterilization validation was confirmed to comply equally as for Technomed Europe devices already released to be legally marketed under K050325, and to conform to all requirements.

Conclusion: The comparison to the predicate devices demonstrates that the Needle Electrodes are safe and effective for its intended use and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 19, 2013

Technomed Europe
c/o Mr. Pierre Vreuls
Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

Re: K130136
Trade/Device Name: Disposable Monopolar Needle Electrode and Disposable Subdermal Needle Electrode
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ and IKT
Dated: June 6, 2013
Received: June 12, 2013

Dear Mr. Vreuls

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 (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. 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.

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 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): __K130136_____

Device Name: Disposable Monopolar Needle Electrode and Disposable Subdermal Needle Electrode

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.

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.07.18 18:26:51 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number ___K130136_____