DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 28, 2015

Natus Manufacturing Limited
Michael Galvin
Manager, Quality and Regulatory Affairs
IDA Business Park
Gort, County Galway
Ireland

Re: K143433
Trade Name: Dantec™ DCN Disposable Concentric Needle Electrodes
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic Electromyograph Needle Electrode
Regulatory Class: Class II
Product Code: IKT
Dated: July 23, 2015
Received: July 27, 2015

Dear Mr. Galvin:

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 27f 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143433

Device Name
DantecTM DCN Disposable Concentric Needle Electrodes

Indications for Use *(Describe)*
DantecTM DCN Disposable Concentric Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals including 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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Section 5: 510(k) Summary

Manufacturer's Name:	Natus Manufacturing Limited IDA Business Park Gort, County Galway Ireland
Official Correspondent:	Michael Galvin Manager, Quality and Regulatory Affairs Natus Manufacturing Limited IDA Business Park Gort, County Galway Ireland
Telephone Number:	+353-(0)91-647451
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Summary Date:	23 July 2015
Trade Names:	Dantec™ DCN Disposable Concentric Needle Electrodes
Common or Usual Name:	Electrode, Needle, Diagnostic Electromyograph
Classification Name :	Diagnostic Electromyograph Needle Electrode
Device Class:	Class II
Product Code:	IKT
Classification Regulation:	21.CFR.890.1385

Classification Panel:	Neurology
Predicate Device:	K112034 Teca™ Elite Disposable Concentric Needle Electrodes
Device Description:	The Dantec™ DCN Disposable Concentric Needle Electrodes are designed as an electrical bipolar recording device for use in electromyography. The Dantec™ DCN Disposable Concentric Needle Electrode consists of an insulated core wire located inside a stainless steel cannula. The hub has a raised bevel indicator, allowing the user to always know the direction of the recording surface. A coaxial hub allows easy connection between needle and the electrode cable.
Intended Use:	Dantec™ DCN Disposable Concentric Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals including electromyograph (EMG) and nerve potential signals.
Technological Comparison:	Dantec™ DCN Disposable Concentric Needle Electrodes employ the same technological characteristics as the predicate device.
Nonclinical Tests:	Mechanical testing: • Hub/Cover tensile testing • Needle/Hub tensile testing • Penetration testing – to measure sliding force • Tip geometry-grind measurements (Pencil Point & Main Bevel) • Impedance testing –needle electrodes should have low impedance
Substantial Equivalence:	The Natus Manufacturing Limited Dantec™ DCN Disposable Concentric Needle Electrodes are equivalent to the device

cleared under K112034 as is presented below in Table 5A Substantial Equivalence Comparison Table.

It has been shown in this 510(k) submission that the differences between the Dantec™ DCN and the predicate device Teca™ Elite do not raise any questions regarding its safety and effectiveness. The Dantec™ DCN device is substantially equivalent to the predicate device as it has the same intended use and similar technological characteristics as the previously cleared predicate devices. The Dantec™ DCN, as designed and manufactured is determined to be substantially equivalent to the referenced predicate devices.

Natus Manufacturing Limited
Traditional 510(k)
Dantec™ DCN Disposable Concentric Needle Electrodes

Table 5A: Substantial Equivalence Comparison Table

Manufacturer	**Natus Manufacturing Limited**	**Natus Neurology Incorporated (formerly Carefusion)**	**Discussion of Differences**
Trade Name	**Dantec™ DCN**	**Teca™ Elite**	
510(k) number	**New Device**	**K112034**	
Product Code	**IKT**	**IKT**	
Regulation number	21.CFR.890.1385	21.CFR.890.1385	Same
Regulation Name	Diagnostic electromyograph needle electrode	Diagnostic electromyograph needle electrode	Same
Intended Use	Dantec™ DCN Disposable Concentric Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals including electromyograph (EMG) and nerve potential signals.	Teca™ Elite Disposable Concentric Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals including electromyograph (EMG) and nerve potential signals.	Same
Environment of Use	Hospital and clinical use under the supervision of a physician.	Hospital and clinical use under the supervision of a physician.	Same
Duration of use	Less than 24 hours	Less than 24 hours	Same
Core Material	Tungsten	Tungsten	Same
Low Friction Lubricant	Silicone	Silicone	Same
Cannula	Stainless Steel	Stainless Steel	Same

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Dantec™ DCN Disposable Concentric Needle Electrodes

Manufacturer	**Natus Manufacturing Limited**	**Natus Neurology Incorporated (formerly Carefusion)**	**Discussion of Differences**
Trade Name	**Dantec™ DCN**	**Teca™ Elite**	
510(k) number	**New Device**	**K112034**	
Product Code	**IKT**	**IKT**	
Sizes	Length Diameter (mm) 25mm 0.30 (30g) 25mm 0.46 (26g) 37mm 0.46 (26g) 50mm 0.46 (26g) 75mm 0.64 (23g)	Length Diameter (mm) 25mm 0.30 (30g) 25mm 0.46 (26g) 37mm 0.46 (26g) 50mm 0.46 (26g) 75mm 0.64 (23g)	Same
Internal Insulating polymer coating between the core and lumen	Polyesterimide/Araldite	Polyesterimide	The Dantec™ DCN Disposable Concentric Needle Electrodes and the predicate device Teca™ Elite Disposable Concentric Needles use the same insulating polymer Polyesterimide. The only slight difference is that the Dantec™ DCN uses this in conjunction with Araldite.
Tip geometry	Trocar Point	Trocar Point	Same
Recording area	Fine gauge = 0.02 mm^2 Medium gauge = 0.07mm^2	Fine gauge = 0.03 mm^2 Medium gauge = 0.07mm^2	The Dantec™ DCN Disposable Concentric Needle Electrodes fine gauge needle has a slightly smaller recording area compared to the predicate device Teca™ Elite Disposable Concentric Needles. However, there is no significant difference in performance as it meets the functional criteria of the predicate device.

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Manufacturer	Natus Manufacturing Limited	Natus Neurology Incorporated (formerly Carefusion)	Discussion of Differences
Trade Name	**Dantec™ DCN**	**Teca™ Elite**	
510(k) number	**New Device**	**K112034**	
Product Code	**IKT**	**IKT**	
Connector Type	The shielded reusable needle holder (cable) is a 59 inch (1.5m) cable with an orientation free needle hub. The proximal end has a 5-pin 240° DIN connector which plugs into most EMG instruments.	The shielded reusable needle holder (cable) is a 59 inch (1.5m) cable with an orientation free needle hub. The proximal end has a 5-pin 240° DIN connector which plugs into most EMG instruments.	Same
Wiring Method	Detachable Lead Wire	Detachable Lead Wire	Same
Provided to the user sterile	Yes	Yes	Same
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Commercially available, medical grade, packaging	Heat sealed blister pack.	Heat sealed blister pack.	Same
Material	Pouch: Tyvek/EVA Protective Tube: Polyethylene	Pouch: Tyvek/EVA Protective Tube: Polyethylene	Same
Packaging	Needles shall be individually pouched and packaged 25 needle pouches per box. 20 cartons per shipper box. Min 1 and Max 54 shipper boxes per pallet.6 Shipper boxes on each level, 3 by 2, can be stacked 9 levels high for the sterilization cycle.	Needles shall be individually pouched and packaged 25 needle pouches per box. 20 cartons per shipper box. Min 1 and Max 54 shipper boxes per pallet. 6 Shipper boxes on each level, 3 by 2, can be stacked 9 levels high for the sterilization cycle.	Same
Shelf life	Three years	Three years	Same
Single-Use	Yes	Yes	Same

Natus Manufacturing Limited
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Dantec™ DCN Disposable Concentric Needle Electrodes

Manufacturer	Natus Manufacturing Limited	Natus Neurology Incorporated (formerly Carefusion)	Discussion of Differences
Trade Name	**Dantec™ DCN**	**Teca™ Elite**	
510(k) number	**New Device**	**K112034**	
Product Code	**IKT**	**IKT**	
Grind Measurements (Pencil Point & Main Bevel)	<table><tr><th>Characteristic</th><th>Specification</th><th>Mean</th></tr><tr><td>Pencil Point Height (mm)</td><td>LSL = 0.345 USL = 0.377</td><td>0.354</td></tr><tr><td>Facet Angle (degrees)</td><td>LSL = 40.0 USL = 46.0</td><td>44.9</td></tr></table>	<table><tr><th>Characteristic</th><th>Specification</th><th>Mean</th></tr><tr><td>Pencil Point Height (mm)</td><td>LSL = 0.345 USL = 0.377</td><td>0.362</td></tr><tr><td>Facet Angle (degrees)</td><td>LSL = 40.0 USL = 46.0</td><td>44.9</td></tr></table>	No significant difference
Needle/Hub Tensile	Specification: >6 lbf Results: <table><tr><th>Mean (lbf)</th></tr><tr><td>22.7</td></tr></table>	Specification: >6 lbf Results: <table><tr><th>Mean (lbf)</th></tr><tr><td>19.7</td></tr></table>	No significant difference. Results for the Dantec™ DCN shows that it meets and exceeds results for the predicate, Teca™ Elite.
Hub/Cover tensile	Specification: >1.2kgf Results: <table><tr><th>Mean (kgf)</th></tr><tr><td>3.9</td></tr></table>	Specification: >1.2kgf Results: <table><tr><th>Mean (kgf)</th></tr><tr><td>3.9</td></tr></table>	Same
Impedance	Specification: <200 K Ohms (KΩ) Results: All samples pass Attribute data - 100% Pass	Specification: <200 K Ohms (KΩ) Results: All samples pass Attribute data - 100% Pass	Same

Summary of Performance Testing-Biocompatibility

Dantec™ DCN Disposable Concentric Needle Electrodes are Invasive Electrodes, classified per ISO 10993-1:2009 as external communicating devices in limited (≤ 24 hours) contact with tissue. Annex A defines that the following evaluation tests need to be considered cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10) and irritation sensitivity (ISO 10993-10).

The materials used in the Dantec™ DCN Disposable Concentric Needle Electrodes are outlined in Table 5B on the following page.
The Biocompatibility Evaluation testing summarized below was conducted on the Dantec™ DCN Disposable Concentric Needle Electrodes to demonstrate compliance of these materials to the following standards:

- USP (87) Biological Reactivity Tests, In Vitro -- elution test. 2014

- ISO 10993-5:2009
  Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10:2010
  Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

- ISO 10993-12:2012
  Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials

Dantec DCN Disposable Concentric Needle Electrodes were tested to conform to USP Endotoxin Reference Standard (USP chapter <161> Transfusion and Infusion Assemblies and Similar Medical Devices). The LAL Inhibition and Enhancement testing using the Turbidimetric method was used. The testing demonstrated that the endotoxin levels of three tested lots were below 20 EU/device.

International Standard BS EN ISO 10993-5: (2009) Biological Evaluation of Medical Devices- Part 5: Tests for in vitro Cytotoxicity
The mean cytotoxicity grade for the extract of the negative control was 0. The extract of the positive control showed evidence of cytotoxicity and had a cytotoxic titre of N/4. The extract of the test item was considered to be non-cytotoxic to L929 cells under the conditions of this test.

Intracutaneous (Intradermal) Reactivity Test in the Rabbit
The study was performed to assess the irritancy potential of polar and non-polar extracts of the test item following intradermal injection in the New Zealand White rabbit. Polar and non-polar extracts of the test item meet the requirements of ISO 10993-10:2010

Local Lymph Node Assay in the Mouse – Polar and Non-Polar Extracts
The results of the tests demonstrated that:
The Polar extract of the test item was considered to be a non-sensitizer under the conditions of the test.
The non-polar extract of the test item was considered to be a non-sensitizer under the conditions of the test.
The polar positive control and non-polar positive control each gave a Stimulation Index of greater than 3.

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Table 5B: Components, Materials and Body Contact

Natus Manufacturing Limited
Traditional 510(k)
Dantec™ DCN Disposable Concentric Needle Electrodes

No	Component Name	Type of contact			Material
		Skin	Blood	Tissue	
1	Cannula	Y	Y	Y	Stainless Steel
2	Cannula Coating	Y	Y	Y	Silicone
3	Colour Cover	Y	N	N	Acrylonitrile-Butadiene-Styrene (ABS)
4	Hub	N/A	N/A	N/A	Brass, copper/nickel plating
5	Core Material	Y	Y	Y	Tungsten
6	Insulator	Y	Y	Y	Polyesterimide/ Araldite
7	Protective Tube	Y	N	N	Polyethylene
8	Pouch	Y	N	N	Tyvek
9	Cartons	Y	N	N	Cardboard

Performance Testing-Bench Testing

Performance Testing was performed on device characteristics of the Dantec™ DCN Disposable Concentric Needle Electrodes. This performance mechanical testing consisted of

- Hub/Cover tensile testing
- Needle/Hub tensile testing
- Penetration testing – to measure sliding force
- Tip geometry-grind measurements (Pencil Point & Main Bevel)
- Impedance testing –completed to demonstrate that Dantec™ DCN Disposable Concentric Needle Electrodes have low impedance

Conclusion

All performance testing and bench testing conducted as outlined above demonstrate that the device met the performance and design specifications.

Verification results indicated that Dantec™ DCN Disposable Concentric Needle Electrodes comply with their predetermined specification and with the applicable Standards detailed below:

- 21 CFR 820.75 Quality System Regulation – Process Validation
- ISO 2859-1:1999 Sampling Procedures For Inspection By Attributes - Part 1: Sampling Schemes Indexed By Acceptance Quality Limit (AQL) For Lot-By-Lot Inspection [Including: Technical Corrigendum 1 (2001), Amendment 1 (2011)]
- ISO 10993-1:2009 Biological Evaluation of medical devices Part 1: Evaluation and testing
- ISO 10993-5:2009 Biological Evaluation of medical devices Part : Tests for in vitro cytotoxicity
- ASTM F 1980 – 07-2011 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Verification activities were conducted to establish the performance and safety characteristics of the Dantec™ DCN Disposable Concentric Needle Electrodes. The results of these activities demonstrate that the Dantec™ DCN Disposable Concentric Needle Electrodes are safe and effective when use in accordance with the intended use, labelling and Instructions for Use.

Therefore, the Dantec™ DCN Disposable Concentric Needle Electrodes are considered substantially equivalent to the predicate device Teca™ Elite Disposable Concentric Needle Electrodes.