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

March 2, 2017

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

Re: K161430
Trade/Device Name: Myoject™ Luer Lock Needle Electrode
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic Electromyograph Needle Electrode
Regulatory Class: Class II
Product Code: IKT
Dated: February 9, 2017
Received: February 13, 2017

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 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for 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)*
K161430

Device Name
Myoject(TM) Luer Lock Needle Electrode

Indications for Use *(Describe)*
The disposable hypodermic monopolar needles are FOR SINGLE USE ONLY in electromyography (EMG) in situations wherein it is desired to insert an electrode, in the form of a probe, into a patient to locate a particular muscle and then inject a medication into that muscle. The hypodermic needle with an open lumen is designed for muscle stimulation, motor unit action potential recording and drug delivery. Once the physician is satisfied with the location, he/she injects a drug therein via the lumen of the needle.

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.

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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
Fax Number:	+353-(0)91-630050
Summary Date:	17 May 2016
Trade Names:	Myoject™ Luer Lock Needle Electrode
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

28 February 2017

Natus Manufacturing Limited
Traditional 510(k)
Myoject™ Luer Lock Needle Electrode

Classification Panel:	Neurology
Predicate Device:	K973444 Teca Myoject Disposable Needle Electrode
Device Description:	The Myoject™ Luer Lock Needle Electrode is a Disposable Hypodermic Needle Electrode
Intended Use:	The disposable hypodermic monopolar needles are FOR SINGLE USE ONLY in electromyography (EMG) in situations wherein it is desired to insert an electrode, in the form of a probe, into a patient to locate a particular muscle and then inject a medication into that muscle. The hypodermic needle with an open lumen is designed for muscle stimulation, motor unit action potential recording and drug delivery. Once the physician is satisfied with the location, he/she injects a drug therein via the lumen of the needle.
Comparison:	The Myoject™ Luer Lock Needle Electrode employ the same technological characteristics as the predicate device.
Nonclinical Tests:	• Tensile testing • Coating thickness • Leak Testing • Tip geometry measurements • Penetration testing • Luer Lock Design
Substantial Equivalence:	The Myoject™ Luer Lock Needle Electrode is equivalent to the device cleared under K973444 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 Myoject™ Luer Lock and the predicate device do not raise any questions regarding its safety and effectiveness. The Myoject™ Luer Lock Needle electrode 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 Myoject™ Luer Lock Needle Electrode, as designed and manufactured is determined to be substantially equivalent to the referenced predicate devices.

Natus Manufacturing Limited
Traditional 510(k)
Myoject™ Luer Lock Needle Electrodes

Table 5A: Substantial Equivalence Comparison Table

Year	**2016**	**20 Nov 1997 (original submission date)**	**Discussion of Differences**
Manufacturer	**Natus Manufacturing Limited**	**TECA Corporation 3 Campus Drive Pleasantville New York 10570**	
Trade Name	**Myoject™ Luer Lock Needle Electrodes**	**Teca Myoject Disposable Needle Electrode**	
510(k) number	**K161430**	**K973444**	
Product Code	**IKT**	**IKT**	
Labelling	Packaging Labels	Packaging Labels	Minor changes to the labelling include change of legal manufacturer name, address and branding. In addition the new device labelling incorporates warnings and harmonized symbols. However, these changes do not raise questions of safety and effectiveness as they provide additional information to the user for the safe and effective use of the device.
Intended Use	The disposable hypodermic monopolar needles are FOR SINGLE USE ONLY in electromyography (EMG) in situations wherein it is desired to insert an electrode, in the form of a	The disposable hypodermic monopolar needles are FOR SINGLE USE ONLY in electromyography (EMG) in situations wherein it is desired to insert an electrode, in the form of a probe, into a patient to	The indications for use is the same as the predicate device expect for the final statement. This information has been omitted, as it is not an indication but a statement that

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510(k) number	**K161430**	**K973444**	
Product Code	**IKT**	**IKT**	
	probe, into a patient to locate a particular muscle and then inject a medication into that muscle. The hypodermic needle with an open lumen is designed for muscle stimulation, motor unit action potential recording and drug delivery. Once the physician is satisfied with the location, he/she injects a drug therein via the lumen of the needle.	locate a particular muscle and then inject a medication into that muscle. The hypodermic needle with an open lumen is designed for muscle stimulation, motor unit action potential recording and drug delivery. Once the physician is satisfied with the location, he/she injects a drug therein via the lumen of the needle. Note: TECA Corp. does not supply any drugs with needle electrodes nor does TECA Corp. offer for sale any form of drugs.	can be included in labeling. The needles are sold on their own as a medical device and are not specifically designated for use with a specific drug. Therefore, this statement is not appropriate for the IFU.
Physical Characteristics	Monopolar Needle	Monopolar Needle	Same
Connector	Single Contact Touch Proof DIN42 802	Single Contact Touch Proof DIN42 802	Same

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Myoject™ Luer Lock Needle Electrodes

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Material of Needle	Stainless 304	Stainless 304	Same
Needle Size (mm)	Needle Diameter: 0.30 0.41 0.46 0.51 0.71	Needle Diameter: 0.30 0.41 0.46 0.51 0.71	Same The dimensions relate to needle diameter
Needle Coating material	PTFE (Xylan 8820 G4075)	PTFE (Ultralon R-605/T-5)	This change resulted from the Accessories development Department's request to reduce the initial penetration force and mitigate against the obsolescence of the Ultralon coating. This change does not raise questions of safety and effectiveness as the needle coating material remains as PTFE however, just the

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			formulation has changed to reduce the initial penetration force to aid easier insertion of the needle. As a result, this reduces patient discomfort when performing EMG examinations.
Hub	Luer Lock/Slip	Luer Slip	This change originated from market place demand for the needles to fit a Luer Lock Syringe. The Luer Lock needle locks into place and as a result is more likely to be seepage free. Therefore, this reduces the risk of medication accidentally leaking from the syringe and possibly causing harm to the patient and user. This does not affect the safety

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			and effectiveness of the device as the overall function of the device remains unchanged, the Luer lock simply adds an additional safety mechanism to the device.
Hub Material	Polypropylene (Exxonmobil) Escorene PP9074 MED	Polycarbonate	The material for this device has changed compared to the predicate device, however comparison with the predicate device demonstrates the material performance is equivalent and they are both variants of polymer materials. There is an insignificant difference between both

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510(k) number	**K161430**	**K973444**	
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			materials; as a result product performance, safety and effectiveness are not affected. In addition, Biocompatibility testing demonstrates there are no new concerns of safety or effectiveness.
Needle grind angle	10-16 degrees conical	10-20 degrees conical	The grind angles have similar specifications; the slight change in the upper range of the grind angle is not a significant change and therefore does not raise new concerns of safety and effectiveness. The change does not alter the diagnostic effects of the device.
Recording area (sqmm)	.19(mm≤) fine and then increases to .89(mm≤) depending on needle size	0.25	There are some differences in recording areas which vary depending on needle size

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			which does not affect the safety and effectiveness of the device; as there are no changes to the diagnostic effects of the device.
Length (mm)	25, 37, 50, 75	25, 37, 50, 75, 100	The 100mm version of the Teca Myoject needle (MJT-10022) (22G) is no longer offered. All other needle sizes are available. This does not raise new concerns of safety and effectiveness as no changes have been made to the devices, the 100mm version has just been made obsolete.
Connecting lead	Myoject: 770±10mm, Form 'ST' moulded 1.5mm touch proof. Cable Length "30" (76cm), terminating in	14 or 26 inches terminated in a 2mm or touchproof plug	For this device the cable has been increased in length to aid ease of use when performing EMG examinations. The

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	1.5mm female touchproof connector.		changes to the cable are minor and do not raise new issues of safety and effectiveness, the cable still serves the same function as the predicate device. In addition, these changes do not interfere with the diagnostic functioning of the device.
Sterilization	Supplied sterilized gamma irradiated	Supplied sterilized gamma irradiated	Same
Protective Sheath	Polypropylene Escorene PP9074 MED (Exxon Mobil)	Polyethylene	The function of the protective sheath is to protect the sharp needle tip in packaging and also provide safety to user when handling the device before and after use. The material for this device has

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Product Code	**IKT**	**IKT**	
			changed compared to the predicate device, however comparison with the predicate device demonstrates the material performance is equivalent and they are both variants of polymer materials. There is an insignificant difference between both materials; as a result product performance, safety and effectiveness are not affected.
Protective Pouch	Tyvek/Mylar	Tyvek/Mylar	Same

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Tip geometry	Trocar Point 15 degree bevel	Lancet Point	Both Lancet and Trocar geometries are routinely used by needle manufacturers in the medical device industry. Trocar point is the preferred geometry for the range of needles to meet market demand.

			This change resulted from modifications to the needle tip geometry enabling improvements to the needle tip sharpness. This change does not result in new issues related to safety and effectiveness; as it increases tip sharpness which reduces the initial penetration force which reduces patient discomfort. This is an improved feature to the device which ultimately functions the same as the predicate device. The diagnostic capabilities of the device are unaffected.
Sterility Assurance Level (SAL)	10 minus 6	10 minus 6	Same

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Summary of Performance Testing-Biocompatibility

Myoject™ Luer Lock 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 Biocompatibility Evaluation testing summarized below was conducted on the Myoject™ Luer Lock Needle Electrodes to demonstrate compliance of these materials to the following standards:

- 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 10993-11:2006
  Biological evaluation of medical devices -- Part 11: Test for Systemic Toxicity
- ISO 10993-12:2012
  Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials

International Standard BS EN ISO 10993-5: (2009) Biological Evaluation of Medical Devices- Part 5: Tests for in vitro Cytotoxicity
The extract of the test item was non-cytotoxic to L929 cells under the conditions of this test.

ISO 10993-10:2010
Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
Section 6.4 Intracutaneous (Intradermal) Reactivity Test

Intracutaneous (Intradermal) Reactivity Test in the Rabbit
The average reaction to the polar test item extract was considered not to be greater than the average reaction for the corresponding control at any observation period.
The average reaction to the non-polar test item extract was considered not to be greater than the average reaction for the corresponding control at any observation period.
Polar and non-polar extracts of the test item meet the requirements of ISO 10993-10: 2010 Intracutaneous (Intradermal) Reactivity Test in the Rabbit.

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

Local Lymph Node Assay in the Mouse – Polar and Non-Polar Extracts
A 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.

ISO 10993-11:2006 Biological evaluation of medical devices - Part 11: Test for Systemic Toxicity
The results are summarizes as follows:
0.9% sodium chloride solution test item extract: PASS
Cottonseed oil test item extract: PASS
The test item complies with ISO 10993-11: 2006, Systemic Toxicity Test in the Mouse.

Performance Testing-Bench Testing

Performance Testing was performed on device characteristics of the Myoject™ Luer Lock Needle Electrodes. This performance testing consisted of

- Tensile testing
- Coating thickness
- Leak Testing
- Tip geometry - grind measurements
- Penetration testing
- Luer Lock Design Verification

Conclusion

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

Verification results indicated that Myoject™ Luer Lock 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 Myoject™ Luer Lock Needle Electrodes. The results of these activities demonstrate that the Myoject™ Luer Lock Needle Electrodes are safe and effective when used in accordance with the intended use, labelling and Instructions for Use.

Therefore, the Myoject™ Luer Lock Needle Electrodes are considered substantially equivalent to the predicate device Teca™ Myoject Disposable Needle Electrodes.