September 29, 2021

MYCO Medical Supplies, Inc.
% E.J. Smith
Consultant
Smith Associates
1468 Harwell Ave.
Crofton, Maryland 21114

Re: K203668
Trade/Device Name: RELI NRFit Epidural Needles, Phoenix NRFit Epidural Needles, RELI NRFit Spinal Needles, Phoenix NRFit Spinal Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: August 30, 2021
Received: August 31, 2021

Dear E.J. Smith:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*

K203668

Device Name

RELI® NRFit® Spinal Needles, RELI® NRFit®Epidural Needles, Phoenix NRFit® Spinal Needles, and Phoenix NRFit® Epidural Needles

Indications for Use *(Describe)*

Spinal and Epidural needles are to be used to inject local anesthetics into a patient to provide regional anesthesia.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510k Summary
K203668

SPONSOR

Company Name: MYCO Medical
Company Address: 2015 Production Drive
Apex, NC 27539

Telephone: 919-460-2535

Contact Person: Sanjiv Kumar
Summary Preparation Date: September 24, 2021

DEVICE NAME

Trade Name: RELI® NRFit® Spinal Needles, RELI® NRFit® Epidural Needles, Phoenix NRFit® Spinal Needles, and Phoenix NRFit® Epidural Needles
Common/Usual Name: Needle, Hypodermic, Single Lumen
Classification Name: Anesthesia Conduction Needle
Regulation Number: 21 CFR 868.5150
Product Code: BSP
Device Class: II

PREDICATE DEVICE

Legally Marketed Equivalent Devices

	K Number	Brand Name	Manufacturer
Primary	K183316	Dr J Spinal and Epidural Needles	Dr. Japan
Reference	K990519	Dr. Japan's Phoenix Brand Spinal and Epidural Needles	Myco Medical Supplies, Inc.
Reference	K142553	UNIEVER Disposable Epidural Anesthesia Needle, UNIEVER Disposable Nerve Blocked	Unisis Corp.

DEVICE DESCRIPTION

RELI® NRFit® Spinal Needles, RELI® NRFit® Epidural Needles, Phoenix NRFit® Spinal Needles, and Phoenix NRFit® Epidural Needles are intended to be used for injection of local anesthetics into a patient to provide regional anesthesia. The Spinal and Epidural needles are supplied in bulk non-sterile, or sterile by ethylene oxide gas in peel open packages and are intended for one-time use.

The RELI® NRFit® Spinal Needles, RELI® NRFit® Epidural Needles, Phoenix NRFit® Spinal Needles, and Phoenix NRFit® Epidural Needles feature an ISO 80369-6 compliant connector that is about 20% smaller than the predicate device. The ISO 80369-6 hub design reduces the risk of cross connection when used with luer connectors developed under the same series of standards.

RELI® NRFit® Spinal Needles and Phoenix NRFit® Spinal Needles are composed of a stainless-steel cannula and stylet, a hub, and plunger. The spinal needle is supplied with either the Quincke Point (K-3 Point) or the Pencil Point tip configuration.

Quincke point spinal needles feature fitted, close tolerance stylet and cannula bevel to minimize coring and trauma; large clear hubs for enhanced tactile feel and visualization of CSF; color coded stylet hub to easily identify gauge size; some sizes are also available with short bevel. Available in

sterile and non-sterile packaging.

Pencil point spinal needles feature an atraumatic point with side-port dispensing to reduce loss of CSF; large clear hubs for enhanced tactile feel and visualization of CSF; color coded stylet hub to easily identify gauge size. Some sizes are available with tapered design to counter bending and minimize flexing during insertion. Available in sterile and non-sterile packaging.

The RELI® NRFit® Epidural Needles and Phoenix NRFit® Epidural Needles are composed of a stainless-steel cannula, a polycarbonate hub and detachable wing, a stainless-steel stylet and plunger as Tuohy (Huber point) tip configuration in various needle gauge sizes and lengths.

Epidural needles feature large clear hub for enhanced tactile feel; wide metric marking for maximum visibility and accuracy in placement; color coded stylet/hub to identify needle gauge size. Epidural needles are available in sterile and non-sterile packaging.

DEVICE INDICATIONS FOR USE

Spinal and Epidural needles are to be used to inject local anesthetics into a patient to provide regional anesthesia.

COMPARISON OF TECHNILOGICAL CHARACTERISTICS

	Subject New Device Myco Medical Supplies, Inc.	**Primary Predicate Dr. Japan**	**Reference Predicate Myco Medical Supplies, Inc.**	**Reference Predicate Unisis Corp.**	**Similarities and Differences**
K Number		K183316	K990519	K142553	
Brand Name	RELI® NRFit® Spinal Needles, RELI® NRFit® Epidural Needles, Phoenix NRFit® Spinal Needles, and Phoenix NRFit® Epidural Needles	Dr J Spinal and Epidural Needles	Dr. Japan's Phoenix Epidural and Spinal Needles	UNIEVER Disposable Epidural Anesthesia Needle, UNIEVER Disposable Nerve Blocked Needle	
Regulation Description	Anesthesia conduction needle	Anesthesia conduction	Anesthesia conduction needle	Anesthesia conduction needle	Same
Regulation No.	21 CFR 868.5150	21 CFR 868.5150	21 CFR 868.5150	21 CFR 868.5150	Same
Product Code	BSP	BSP	BSP	BSP	Same

	Subject New Device Myco Medical Supplies, Inc.	Primary Predicate Dr. Japan	Reference Predicate Myco Medical Supplies, Inc.	Reference Predicate Unisis Corp.	Similarities and Differences
Indications for Use	Spinal and Epidural needles are to be used to inject local anesthetics into a patient to provide regional anesthesia.	Dr. J Spinal and Epidural needles are intended to be used for injection of local anesthetics into a patient to provide regional anesthesia	Spinal and Epidural needles are to be used to inject local anesthetics into a patient to provide regional anesthesia	The Uniever Disposable Epidural Anesthesia Needle is intended to be used for injection into the epidural space / or placing the epidural catheter into the epidural space. Uniever Disposable Nerve Blockade Needle is intended to be used for injection of local anesthetic agent near the nerve for temporary pain control.	Same
Device Design					
Needle Hub	NRFit® connector conforming to ISO 80369-6 for neuraxial device	Hub luer taper connector conforming to ISO 80369-7	Hub luer taper connector conforming to ISO 594	Hub luer taper connector conforming to ISO 594	Different The subject device differs from the predicates only in hub dimensions. ISO 80369-6 specifies a 6% taper hub vs. 5% taper hub in ISO 80369-7 (ISO 594).

	Subject New Device Myco Medical Supplies, Inc.	Primary Predicate Dr. Japan	Reference Predicate Myco Medical Supplies, Inc.	Reference Predicate Unisis Corp.	Similarities and Differences
Operating Principle, Spinal Needle	Spinal anesthesia is a form of regional anesthesia involving the injection of a local anesthetic into the subarachnoid space through a spinal needle. Regardless of the anesthetic agent used, the desired effect is to block the transmission of afferent nerve signals from peripheral nociceptors. Sensory signals from the site are blocked, thereby eliminating pain. Spinal anesthetics are typically limited to procedures involving most structures below the upper abdomen. To administer a spinal anesthetic to higher levels may affect the ability to breathe by paralyzing the intercostal respiratory muscles, or even the diaphragm in extreme cases, as well as the body's ability to control the heart rate via the cardiac accelerator fibers.	Spinal anesthesia is a form of regional anesthesia involving the injection of a local anesthetic into the subarachnoid space through a spinal needle. Regardless of the anesthetic agent used, the desired effect is to block the transmission of afferent nerve signals from peripheral nociceptors. Sensory signals from the site are blocked, thereby eliminating pain.	Spinal anesthesia is a form of regional anesthesia involving the injection of a local anesthetic into the subarachnoid space through a spinal needle. Regardless of the anesthetic agent used, the desired effect is to block the transmission of afferent nerve signals from peripheral nociceptors. Sensory signals from the site are blocked, thereby eliminating pain. Spinal anesthetics are typically limited to procedures involving most structures below the upper abdomen. To administer a spinal anesthetic to higher levels may affect the ability to breathe by paralyzing the intercostal respiratory muscles, or even the diaphragm in extreme cases, as well as the body's ability to control the heart rate via the cardiac accelerator fibers.	Spinal anesthesia is a form of regional anesthesia involving the injection of a local anesthetic into the subarachnoid space through a spinal needle. Regardless of the anesthetic agent used, the desired effect is to block the transmission of afferent nerve signals from peripheral nociceptors. Sensory signals from the site are blocked, thereby eliminating pain. Spinal anesthetics are typically limited to procedures involving most structures below the upper abdomen. To administer a spinal anesthetic to higher levels may affect the ability to breathe by paralyzing the intercostal respiratory muscles, or even the diaphragm in extreme cases, as well as the body's ability to control the heart rate via the cardiac accelerator fibers.	Same

	Subject New Device Myco Medical Supplies, Inc.	Primary Predicate Dr. Japan	Reference Predicate Myco Medical Supplies, Inc.	Reference Predicate Unisis Corp.	Similarities and Differences
Operating Principle, Epidural Needle	Epidural anesthesia is a regional anesthesia that blocks pain in a particular region of the body. An epidural needle is used to inject local anesthetic agent into the epidural space of the spinal cord to block the pain. To provide continuous epidural anesthesia, a small hollow catheter is threaded through the epidural needle into the epidural space and left there while the needle is removed.	Epidural anesthesia is a regional anesthesia that blocks pain in a particular region of the body. An epidural needle is used to inject local anesthetic agent into the epidural space of the spinal cord to block the pain. To provide continuous epidural anesthesia, a small hollow catheter is threaded through the epidural needle into the epidural space and left there while the needle is removed.	Epidural anesthesia is a regional anesthesia that blocks pain in a particular region of the body. An epidural needle is used to inject local anesthetic agent into the epidural space of the spinal cord to block the pain. To provide continuous epidural anesthesia, a small hollow catheter is threaded through the epidural needle into the epidural space and left there while the needle is removed.	Epidural anesthesia is a regional anesthesia that blocks pain in a particular region of the body. An epidural needle is used to inject local anesthetic agent into the epidural space of the spinal cord to block the pain. To provide continuous epidural anesthesia, a small hollow catheter is threaded through the epidural needle into the epidural space and left there while the needle is removed.	Same
Intended Patient Population	Adult and child	Adult and child	Adult and child	Not Specified	Same, though Unisis device patient population is not specified.
Material Specifications					
Needle/ Cannula material	Cold-rolled stainless steel (JIS G4305-SUS304)	Cold-rolled stainless steel (JIS G4305-SUS304)	Cold-rolled stainless steel (JIS G4305-SUS304)	Stainless steel SUS304	Same
Cannula depth markings	The system to cause a chemical change of the metal ion on the surface to a black color by electrolysis without changing the material of cannula.	The system to cause a chemical change of the metal ion on the surface to a black color by electrolysis without changing the material of cannula.	The system to cause a chemical change of the metal ion on the surface to a black color by electrolysis without changing the material of cannula.	Cannula depth markings are present	Same
Stylet material	Stainless steel wire for spring (JIS G4314-SUS304)	Stainless steel wire for spring (JIS G4314-SUS304)	Stainless steel wire for spring (JIS G4314-SUS304)	Plastic	Same Different for Unisis Epidural Needle
Hub material	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate	Same

	Subject New Device Myco Medical Supplies, Inc.	Primary Predicate Dr. Japan	Reference Predicate Myco Medical Supplies, Inc.	Reference Predicate Unisis Corp.	Similarities and Differences
Gauge length/color depiction	Per ISO 6009	Per ISO 6009	Per ISO 6009	Per ISO 6009	Same
Plunger/ Stylet Hub	Polycarbonate	Polycarbonate	Polycarbonate	Polycarbonate	Same
Final Needle assembly protection	Protector (polyethylene)	Protector (polyethylene)	Protector (polyethylene)	Protective Sheath	Same
Sterilization Method	Supplied Sterile via EtO and Non-sterile intended to be sterilized via EtO prior to end use. •ISO 11135 •SAL 10^{-6} •Maximum EO residual levels comply with ISO 10993-7	Sterile EO (=ETO) per ISO 11135:2014 SAL 10^{-6} Maximum EO levels comply with ISO 10993-7:2008	Sterile via EtO	Sterile via EtO	Same

Discussion of Technological Differences

Similarities

The intended use statement, indications for use, technical specifications and descriptions of the needle, materials used, sterilization method and sterility assurance level, and biocompatibility are identical to predicate device previously cleared.

Differences

The only difference between the predicate devices and the subject device is the design of the needle´s hub. The predicate device was cleared with a hub luer taper connector conforming to ISO 594. The subject devices are equipped with a NRFit connector conforming to ISO 80369-6 for neuraxial devices. The subject device removes a brass bush/washer component that was part of the predicate device detachable wing Tuohy (Huber point) Epidural needle hub. The NRFit® Spinal and Epidural needle hubs for the subject device are composed of the same polycarbonate material as the predicate device. The difference of the needle's hub design raises no issues of safety and effectiveness.

Comparison Table of Spinal Needles

Subject Device			Primary Predicate Device *K183316*			Reference Predicate Device *K990519*		
Spinal Needles			Spinal Needles			Spinal Needles		
Gauge	Length Inches	Tip Configuration	Gauge	Length Inches	Tip Configuration	Gauge	Length Inches	Tip Configuration
20 – 27	2.5 - 5	Pencil Point	25 - 27	3.5	Pencil Point	22 - 27	1.5 – 5	Pencil Point
18 – 29	1.5 – 8	Quincke (K-3 Point)	18 – 27	3.5	Quincke (K-3 Point)	18 – 29	1 – 7	Quincke (K-3 Point)

These range of gauge sizes offered fall within the ranges of identified predicates. The range of RELI® NRFit® and Phoenix NRFit® Spinal Needle length has been expanded based on engineering drawings and to meet clinical requirements for the patient population. These additional line items raise no new issues of safety and effectiveness.

Comparison Table of Epidural Needles

Subject Device			Primary Predicate Device *K183316*			Reference Predicate Device K142553		
Epidural Needles			Epidural Needles			Epidural Needles		
Gauge	Length Inches	Tip Configuration	Gauge	Length Inches	Tip Configuration	Gauge	Length Inches	Tip Configuration
16 – 22	2.5 – 6	Tuohy (Huber)	16 – 20	3.5	Tuohy (Huber)	14 - 25	1 – 6	Tuohy (Huber)

All the gauge sizes and lengths offered for the RELI® NRFit® and Phoenix NRFit® Epidural Needles fall within the ranges for standard epidural needles offered by the identified predicates. These additional line items raise no new issues of safety and effectiveness.

PERFORMANCE TESTING – NON-CLINICAL

The following biocompatibility and functional performance testing were conducted on the RELI® NRFit® Spinal Needles, RELI® NRFit® Epidural Needles, Phoenix NRFit® Spinal Needles, and Phoenix NRFit® Epidural Needles:

Biocompatibility

Spinal Needles are classified as External communicating device, Blood path, indirect Limited (<24h).

Epidural Needles are classified as External communicating device, Tissue contact, Limited (<24h).

Testing per ISO 10993-1:2018	
Cytotoxicity	Per ISO 10993-5, Non-Cytotoxic
Sensitization	Per ISO 10993-10, Non-Sensitizer
Intracutaneous Reactivity	Per ISO 10993-10, Non-Irritant
Acute Systemic Toxicity	Per ISO 10993-11, Non-Toxic
Material Mediated Pyrogenicity	Per ISO 10993-11 and USP <151>, Non-Pyrogenic
Hemocompatibility	Per ISO 10993-4, Non-Hemolytic
Chemical Characterization	Per ISO 10993-18, acceptable extractables/leachables profile

Performance Testing

Functional Test	Test Standard
Stability Test Bonding to Hub	Per ISO 7864:2016
Penetration Force and Drag Force for Needles	Per ISO 7864:2016
Breakage Test	Per ISO 9626:2016
Stability Test Bending Rigidity	Per ISO 9626:2016
Positive pressure leakage	Per ISO 80369-6:2016
Resistance to separation from axial load	Per ISO 80369-6:2016
Resistance to separation from unscrewing	Per ISO 80369-6:2016
Resistance to overriding	Per ISO 80369-6:2016
Stress Cracking	Per ISO 80369-6:2016

Additional Testing Standards

Test	Standard
Particulate Matter	USP <788>
LAL Endotoxin	AAMI 72, USP <85>, ≤ 2.15 EU/device

Sterilization and Shelf Life

Parameters	Responses
Method of Sterilization	EtO
Method of Validation	ISO 11135-1
Sterility Assurance Level (SAL)	10^{-6}
Pyrogen Testing	ISO 10993-11
Maximum Levels of Residues of EO, Ethylene Glycol and Ethylene Chlorohydrin	
EtO	below allowable limits per ISO 10993-7
ECH	below allowable limits per ISO 10993-7
Shelf Life	
2-Years	

CONCLUSION

The subject device and the predicate have the same intended use and the technological differences do not raise different questions of safety and effectiveness. Based upon the intended use, principles of operation, materials, technology characteristics and safety performance testing it is the conclusion of MYCO Medical Supplies, Inc., that the RELI® NRFit® Spinal Needles, RELI® NRFit® Epidural Needles, Phoenix NRFit® Spinal Needles, and Phoenix NRFit® Epidural Needles are substantially equivalent to the predicate device.