



February 2, 2018

International Medical Development, Inc.
% John Lincoln
Principal Consultant
J.E. Lincoln and Associates
P.O. Box 2786
St. George, Utah 84771

Re: K170112
Trade/Device Name: IMD's Lumbar Puncture Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: December 26, 2017
Received: January 2, 2018

Dear John Lincoln:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170112

Device Name

IMD's Lumbar Puncture Needle

Indications for Use (Describe)

IMD's Lumbar Puncture Needle, a single patient use needle; it is intended to gain entry into or puncture the spinal cavity permitting injecting (including anesthesia) / withdrawal of fluids for purpose of diagnostic lumbar puncture, myelography discography procedures.

The device is intended for adult and pediatric patients.

It is to be used only under the direction of a licensed clinician.

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."

510(k) Summary

SUBMITTED BY: IMD INC.
560 Hwy 39 P O Box 510
Huntsville UT 84317
(800)-824-8223, or (801) 745-4700

01. DEVICE NAME (Trade/common, and classification):

Common Name: Anesthesia Conduction Needle

Trade Name: IMD's Lumbar Puncture Needle

Product Code: BSP

Regulation Nos.: 868.5150

02. PREDICATE AND REFERENCE DEVICES:

2.1 Predicate Device:

Pajunct's Lumber Puncture Needle, K160294, Regulation Number 868.5150, Class II, Product Code BSP, Panel: Anesthesiology, cleared 10/21/2016; Same Intended Use, materials and method of manufacture are similar; see matrix below;

2.2 Reference Devices:

This submission is identical to the following reference devices in materials, method of assembly / testing, and packaging / sterilization; but one with the addition of side fenestrations (K113662), and all with different Indications for Use;

IMD's Fenestrated Nerve Block Needle (Closed-end Tip / Pencil Point), K113662 Regulation Number 868.5140, Class II, Product Code CAZ, Panel: Anesthesiology, cleared 04/20/2012;

IMD's Anesthesia Needles (Touhy, Quincke, and Pencil Point), K070354 Regulation Number 868.5150, Class II, Product Code BSP, Panel: Anesthesiology, cleared 10/05/2007; and

IMD's Anesthetic Needle (Gertie Marx), K931644, Regulation Number 868.5150,

Device Comparison Table:

COMPARATIVE (SE) INFORMATION MATRIX

	IMD's Lumbar Puncture Needle – K170112	Pujunk Lumbar Puncture Needle – K160294	IMD's Fenestrated Nerve Block Needle – K113662	IMD's, Anesthetic Needles: Touhy, Quincke, Pencil Point -- K070354
Intended Use:	Single patient use lumbar puncture needle used gain entry into or puncture the spinal cavity permitting injecting (including anesthesia) / withdrawal of fluids for purposed of diagnostic lumbar puncture, myelography discography procedures. It is to be used only under the direction of a licensed clinician.	Single patient use lumbar puncture needle used gain entry into or puncture the spinal cavity permitting injecting (including anesthesia) / withdrawal of fluids for purposed of diagnostic lumbar puncture, myelography discography procedures. It is to be used only under the direction of a licensed clinician.	Single patient use peripheral nerve block needle used to provide local or regional nerve blocking by the injecting of a local anesthesia. It is to be used only under the direction of a licensed clinician.	Single patient use needles intended for the transient delivery of anesthetics to provide regional anesthesia ... placement of an epidural catheter... used only under the direction of a licensed clinician.
Length:	3.5 in. (90 mm) - 5.0 in (150 mm)	Various (90 – 150 mm)	3.5 in. (90 mm) and 5.0 in. (150 mm)	Various (22 ga. = 3.5 in. / 90 mm)
Gauge:	Various (18 - 27 ga.)	Various (18 - 20 ga.)	20 ga.	Various (18, 22, 25 ga.)
Tip Configuration :	Pencil Point	Sprotte and Quincke	Pencil Point	Pencil Point, et al
Materials:				
Needle / Cannula	304 Stainless steel	304 Stainless steel	304 Stainless steel	304 Stainless steel
Hub	K-Resin (SBC); or Cyrolite acrylic	Polycarbonate	K-Resin (SBC); or Cyrolite acrylic	K-resin (SBC); or Cyrolite acrylic
Stylet	Stainless steel	Stainless steel	Stainless steel	Stainless steel
Methods of Manufacture:	Identical to the reference IMD Needles; using same needle manufacturer	Similar to IMD	Identical to the IMD Needles; using same needle manufacturer	Identical to the IMD Needles; using same needle manufacturer
Cannula:	One (side) fenestration	One fenestration	Multiple side fenestrations	One fenestration
Biocompatibility:	Yes, per ISO 10993	Yes, per ISO 10993	Yes, per ISO 10993	Yes, per ISO 10993
Packaging:	Same header bag / pouches; using same contract	Header bag / pouches.	Same header bag / pouches; using same contract	Same header bag / pouches; using same contract

	packaging company (IPM) with same validated sealers		packaging company (IPM) with same validated sealers	packaging company (IPM) with same validated sealers
Product Labeling:	Single- and 10-unit	Single- and multiple	Single- and 10-unit	Single- and 10-unit
Sterilization:	100% EtO	100% EtO	100% EtO	100% EtO
	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic
	Sterigenics, SLC UT: EO steriliz'n, cycle 870	Unknown	Sterigenics, SLC UT: EO steriliz'n, cycle 870	Sterigenics, SLC UT: EO sterilization, cycle 870
	Nelson Labs, SLC UT: BI testing	Unknown	Nelson Labs, SLC UT: BI testing	Nelson Labs, SLC UT: BI testing
	Nelson Labs: EO validation (ISO 11135)	Unknown	Nelson Labs: EO validation (ISO 11135)	Nelson Labs: EO validation (ISO 11135)

Note: Only the needle / cannula comes into contact with the patient in routine use.

03. DESCRIPTION:

The IMD Inc. Lumbar Puncture Needle shares major similarities with the predicate device(s), in as much as the configuration, materials, area of use, and are identical to the IMD reference devices.

It consists of an introducer, stylet, and pencil-point needle, with plastic hubs, and stainless steel cannula. Offered in 18-27 gauges, and 3.5 in. (90 mm) and 5.0 in (124 mm) lengths.

04. INDICATIONS FOR USE / INTENDED USE:

IMD's Lumbar Puncture Needle, a single patient use needle; it is intended to gain entry into or puncture the spinal cavity permitting injecting (including anesthesia) / withdrawal of fluids for purpose of diagnostic lumbar puncture, myelography discography procedures.

The device is intended for adult and pediatric patients.

It is to be used only under the direction of a licensed clinician.

05. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:

The IMD's Lumbar Puncture shares the identical configuration, features, materials, methods of manufacture / manufacturer, testing, packaging / packager, and sterilization / sterilizer as the reference needles (IMD's). Biocompatibility and Performance testing has been provided in the reference device submissions, which support substantial equivalence (SE).

It's Indications for Use is similar to the predicate device and the intended use is the same. The indications differ in minor semantics and include the prescription device statement. Therefore, the different semantics and prescription statement included in the IFU does not change the intended use, and does not affect the safety and effectiveness of the device when used as labeled

It is therefore substantially equivalent to the predicate device listed above.

In addition:

- No record of unexpected patient problems or adverse reactions were found in our review of the FDA's MAUDE, Safety Alert, and MDR databases;
- The device and its packaging was tested by an independent lab for the following:

Test:	References:
Product Sterility	Cleanroom, Direct transfer method, Nelson Labs PSC 110, STP0077 Rev 07, USP General Chapter 71, ANSI/AAMI/ISO 11737-2, EP 2.6.1, JP and 21 CFR 610.12
Bacteriostasis and Fungistasis	Method II: Direct Inoculation, Nelson Labs BFS 120, USP <71>, EP 2.6.1 and <JP XV, 54>; and AAMI/ISO 11737-2.

Production Lots are also subjected to inspection / testing by Incoming QC, in-process QC, and finished goods QC, and monitored in the field by means of our CAPA system.

06. CONCLUSION:

There are no substantive differences between the device defined in this 510(k) submission and the predicate and reference devices. It is identical or similar in configuration, material and manufacturing / sterilization technologies that are currently used in other similar medical devices. It was developed and documented under IMD's Quality Management System, under the Quality System Regulation, 21 CFR Part 820, including design / change control, and is verified / validated to applicable standards / guidance documents, including vendors' and our SOPs. It is designed and manufactured to be as safe and as effective as the predicate device when used as intended, under a licensed clinician's supervision. IMD's Lumbar Puncture Needle share similar or identical Indications for Use, and characteristics, materials, manufacturer, sterilization, and functional features, and thus are substantially equivalent to the currently marketed predicate and reference devices, cited above.