July 29, 2022

Global Medikit Limited
℅ Atonu Dutta
CEO
Alceon
201-203 Tilak Complex, Jetalpur Road
Vadodara, Gujarat 390007
India

Re: K212982
Trade/Device Name: Medispine - Spinal Needle, Glospine - Spinal Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: June 30, 2022
Received: July 5, 2022

Dear Atonu Dutta:

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 and Part 809); 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,

for 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)*
K212982

Device Name

Medispine - Spinal Needle and Glospine - Spinal Needle

Indications for Use *(Describe)*
Spinal Needle (Quincke Bevel and Pencil Point) is intended for injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management. The device is intended to be used in a professional healthcare environment and not tested for MRI safety.

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.

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1. Submission Sponsor

Global Medikit Limited,
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2. Submission Correspondent

Alceon
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Contact Person: Mr. Atonu Dutta
Phone: (+91) 9925023428
Email: regulatory@alceon.in

3. Date Summary Prepared:

9th September 2021

4. Device name & classification:

Trade/Proprietary Name: Medispine – Spinal Needle and Glospine – Spinal Needle
Common/Usual Name: Anesthesia conduction needle
Device classification Regulation: 21CFR Part 868.5150
Product Code: BSP
Device Class: Class 2
Classification Panel: Anesthesiology

5. Predicate Device

Trade/Proprietary Name: Spinal Anesthesia Needles
Manufacturer: Zhejiang kindly medical devices Co., Ltd
Common/Usual Name: Anesthesia conduction needle
510(K): K171518
Device classification Regulation: 21CFR Part 868.5150
Product Code: BSP
Device Class: Class 2

Classification Panel: Anesthesiology

6. Device Description

Spinal Needles are long, flexible needles of small gauge (typically 18G to 27G) which are available with different types of tips: Pencil point and Quincke bevel. The Spinal Needles are available in a series of combination of needle size and length.

The smaller size needles of Pencil point tip are provided with introducer needles to provide support for accessing the tough tissues.

Spinal needles have a removable stylet that completely occludes the lumen to avoid block. The stylet is withdrawn after the spinal anesthesia needle has penetrated into the subarachnoid space for injecting anesthetic.

The needle hub is luer connector (6% luer taper).

7. Indications for Use

Spinal Needle (Quincke Bevel and Pencil Point) is intended for injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management. The device is intended to be used in a professional healthcare environment and not tested for MRI safety.

8. Comparison to predicate device

The following table compares the subject device to the predicate device with respect to their indications for use, technology and performance testing, thus demonstrating the basis for determination of substantial equivalence between these devices.

Description	Subject Device	Predicate Device	Comparison
Trade/Device Name	Spinal Needle	Spinal Anesthesia Needles	-
Manufacturer	Global Medikit Limited	Zhejiang kindly medical devices Co., Ltd	-
510 (K)	Applied	K171518	-
Class	Class 2	Class 2	-
Regulatory number	21 CFR Part 868.5150	21 CFR Part 868.5150	-
Product code	BSP	BSP	-
Clinical			
Intended Use	Spinal Needle (Quincke Bevel and Pencil Point)	The Spinal Anesthesia Needles are	Same

Description	Subject Device	Predicate Device	Comparison
	is intended for injection of local anesthetics into the subarachnoid space to provide spinal anesthesia for pain management.	intended to be used for injection of local anesthetic agent into the subarachnoid cavity for pain management.	
Technical specification			
Product Configuration	Stylet Hub Stylet Needle Tube Needle Hub Needle Hub Insert Protective Cap of Needle	Stylet Hub Stylet Needle Tube Needle Hub Needle Hub Insert Protective Cap of Needle	Same
Needle gauge	18G-27G	18G-27G	Same
Needle length	70 mm, 90 mm, 120 mm	40mm, 50mm, 65mm, 70mm, 80mm, 90mm, 120mm	Same
Needle tip configuration	Quincke bevel and Pencil point	Quincke and Pencile	Same
Sterility	EO sterilized	EO Sterilized	Same
Single use	Single use	Single Use	Same
Shelf life	5 years	3 years	Similar#
Label/Labeling	Conform with 21 CFR 801	Conform with 21 CFR 801	Same
Product Performance	Complies with: ISO 9626:2016, ISO 7864:2016, ISO 594-1:1986, ISO 594-2:1998 ISO 80369-7:2016 ISO 6009:2016	Complies with: ISO 9626:1991 AMD 1:2001, ISO 7864:1993, ISO 594-1:1986, ISO 594-2:1998	Same
Biological			
Needle Material	Stainless steel	Stainless steel	Same

Description	Subject Device	Predicate Device	Comparison
Biocompatibility	Conform with ISO 10993	Conform with ISO 10993	Same

The shelf life of subject device is verified through the stability studies conducted for the device and hence, there are no additional risk generated due to the difference observed in the shelf life of the proposed device compared to the predicate device.

Hence, the device is considered as substantially equivalent to the predicate device.

9. Summary of non-clinical testing

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ISO 7864:2016 4th edition: Sterile hypodermic needles for single use - Requirements and test methods
- ISO 9626:2016 2nd edition: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 594-1:1986 1st edition: Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- ISO 594-2:1998 2nd edition: Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- ISO 80369-7:2016 1st edition: Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
- ISO 6009:2016 4th edition: Hypodermic needles for single use - Colour coding for identification.

The biocompatibility tests were performed in accordance with the following standards:

- ISO 10993-1:2018 5th edition: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-4:2017 3rd edition: Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 3rd edition: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 4th edition: Biological evaluation of medical devices - Part 10: Tests for skin sensitization

- ISO 10993-23:2021:1st edition: Biological evaluation of medical devices – Part 23: Tests for irritation
- ISO 10993-11:2017 3rd edition: Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

The device is sterilized by Ethylene oxide sterilization method, the sterilization process was validated as per ISO 11135:2014/AMD 1:2018 2nd edition: Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.

The EO residual were tested which meets the requirements of ISO 10993-7:2008 2nd edition: Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.

The Bacterial endotoxin testing of subject devices was performed by "Gel-Clot Method" and meets the requirement of USP.

Packaging validation and transport study tests were conducted in accordance with the following standard:

- ISO 11607-1:2019 2nd edition: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2019 2nd edition: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM D4169-16: Standard Practice for Performance Testing of Shipping Containers and Systems

10. Summary of Clinical Testing

No clinical data was included in this premarket application submission.

11. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.