February 13, 2025

JMT Co., Ltd
% Dave Kim
Regulatory Affairs Consultant
Mtech Group LLC
7505 Fannin St. Suite 610
Houston, Texas 77054

Re: K241410
Trade/Device Name: EDEN ControlCath
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia conduction catheter
Regulatory Class: Class II
Product Code: BSO
Dated: January 14, 2025
Received: January 14, 2025

Dear Dave Kim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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)*
K241410

Device Name

EDEN ControlCath

Indications for Use *(Describe)*

EDEN ControlCath is used for delivery of drugs that have been indicated for the epidural space.

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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510(k) Summary
K241410

The following 510(k) summary is being submitted as required by 21 CFR 868.5120;

1. Submitter:

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Date Prepared: April 30, 2024

2. Device Identification

Device Trade Name	EDEN ControlCath
Common Name	Anesthesia conduction catheter
Classification Name, Number	Anesthesia conduction catheter (21 CFR 868.5120)
Device Classification	II
Product Code	BSO

3. Predicated or legally marketed devices which are substantially equivalent

Predicated device: K150789, "SPINAUT-E, SPINAUT-I", manufactured by "IMEDICOM Co., Ltd."

4. Device Description

EDEN ControlCath consists of a flexible catheter, steering handle, and a port for access to the lumen. The catheter has built in steering mechanism that allows for guiding the soft tip through the epidural space and soft tissues for optimal access to the source of distress.
The port facilitates the connection of syringes to deliver therapeutic agents by physicians as appropriate to their diagnosis. It is supplied sterile and it is for single use.

5. Intended Patient Population

The device under evaluation may be used in patients who meet the indications and have none of the contraindications.
The general principles of good patient selection and sound surgical judgement apply to the procedures. Pre-operative planning and careful surgical technique are essential to achieve optimal results. Consideration of anatomical loading, soft tissue condition and component placement is critical to minimizing a variety of postoperative complications.
This device is intended for ages above 18 years old

6. Statement of Indication for use

EDEN ControlCath is used for delivery of drugs that have been indicated for the epidural space.

7. Non-clinical Test Conclusion

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

○ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
○ ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
○ ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
○ ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
○ ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation
○ ISO 10555-1 Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements
○ ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
○ ISO 80369-20 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
○ ISO 11135 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
○ ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials
○ ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
○ ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Bench test results allowed to conclude that EDEN ControlCath is substantially equivalent to the predicate devices for its intended use.

8. Clinical Test Conclusion

Clinical testing was not required for this submission.

9. Technical Characteristics and Substantial Equivalence

The **EDEN ControlCath** is substantially equivalent to **SPINAUT-E, SPINAUT-I (K150789)**. The following comparison table is presented to demonstrate substantial equivalence.
The **EDEN ControlCath** does not have a new intended use. It shows the same specifications as the predicate devices in most parameters. Also, there are no significant differences in some parameters between the **EDEN ControlCath** and **SPINAUT-E, SPINAUT-I (K150789)**.
The **EDEN ControlCath** and **SPINAUT-E, SPINAUT-I (K150789)** have been demonstrated as substantial equivalence in technical aspects.

Table 1. General Device Characteristics Comparison Table

	Candidate Device	Predicate Device	Substantial Equivalence Analysis
510(k) Number	K241410	K150789	-
Device Name	EDEN ControlCath	SPINAUT-E SPINAUT-I	-
Manufacturer	JMT Co., Ltd.	IMEDICOM Co., Ltd.	-
Product Code	BSO	BSO	-
Indication for Use	EDEN ControlCath is used for delivery of drugs that have been indicated for the epidural space	SPINAUT-E is used for delivery of drugs that have been indicated for the epidural space. SPINAUT-I is intended for the percutaneous introduction and	Substantial Equivalence

		placement of an epidural catheter.	
Diameter (O.D.) of Catheter	EDEN CC & EDEN CC(A) : Ø 1.73, EDEN CC(2.1) & EDEN CC(2.1A) : Ø 2.1	1.7mm	No significant difference: The subject device passed the test criteria for the side-by-side test(*).
Length of Catheter	300mm	300mm/ 315mm/ 330mm	No significant difference: The subject device passed the test criteria for the side-by-side test(*).
Key Performance Specification/Characteristics	-. Catheter: Tensile Load, Liquid Leakage, Corrosion Resistance, Fatigue, Flexural Strength -. Trocar: Outer and Inner Surface, Flexural Strength, Pull Out, Elasticity, Pierce -. Sheath: Tensile Load, Flexural Strength -. Guide Wire: Strength	-. Catheter: Tensile Load, Liquid Leakage, Corrosion Resistance, Fatigue, Flexural Strength -. Trocar: Outer and Inner Surface, Flexural Strength, Pull Out, Elasticity, Pierce -. Sheath: Tensile Load, Flexural Strength -. Guide Wire: Strength	Same as predicate device(*)
Compatible Syringe	Recommended for use with 10cc syringe	Recommended for use with 10cc syringe	Same as predicate device
Infusion port	One port	One port	Same as predicate
Raw Materials	ABS, Silicone, PVC, PE, PA, SUS 304, PEEK, SODIUM ALUMINO SULPHO SILICATE, Titanium dioxide	SUS 304, PU, ABS, PE, PTFE, ABS, Polyurethane	No significant difference: The subject device passed the test criteria for the bench test according to the recognized consensus standard (ISO 10993-1 Series).
Steering	Steerable	Steerable	Same as predicate
Single use	Yes	Yes	Same as predicate
Components	Catheter, Trocar, Catheter sheath, Guide wire	Epidural catheter, guide wire, catheter introducer, introducer needle, and needle cap	Substantial Equivalence
Biocompatibility	All patients directly/indirectly contacting materials are compliant with ISO10993 requirements.	All patients directly/indirectly contacting materials are compliant with ISO10993 requirements.	Same as predicate
Endoscope capable	Incapable	Incapable	Same as predicate
Sterilization	E.O gas Sterilization	Gamma Sterilization	No significant difference: The subject device passed the test criteria for the bench test according to the recognized consensus

			standard (ISO 11135).

The subject device and predicate device have no significant differences in most parameters and the differences do not affect the substantial equivalence of the subject device when compared to the predicate device.

10.	**Conclusion**	Based on the testing results and specifications, JMT Co., Ltd. concludes that the subject device is substantially equivalent to the predicate device.
11.	**Declarations**	This summary includes only information that is also covered in the body of the 510(k). This summary does not contain any puffery or unsubstantiated labeling claims.