November 2, 2023

GuideStar Medical Devices
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K233056
Trade/Device Name: EpiZact
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: October 23, 2023
Received: October 23, 2023

Dear Prithul Bom:

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.

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 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)*

Device Name
EpiZact

Indications for Use *(Describe)*
EpiZact is intended for use with an epidural needle for detecting a loss of resistance, which aids a clinician in verifying needle tip placement in 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

1 SUBMITTER

Submitter: GuideStar Medical Devices Inc.
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Date of Preparation: July 24, 2023

2 DEVICE INFORMATION

Trade Name: EpiZact
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF

3 PREDICATE DEVICE

Predicate Trade Name: EpiFaith Syringe
Premarket Notification: K192421
Manufacturer: Flat Medical Co., Ltd
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF

4 DEVICE DESCRIPTION

EpiZact is a self-pressurizing piston syringe that uses the same loss of resistance technique used by physicians to detect the epidural space. The device is single use, sterile, hand-held, manually powered, and designed to connect to standard epidural Tuohy needles (16-18 gauge) with a standard Luer connector.

EpiZact provides tactile feedback, in addition to visual feedback, when a loss of resistance is detected. The tactile feedback is also designed to help reduce the forward motion of the needle upon detection of loss of resistance. The device is comprised of copolyester plastic, stainless steel springs, silicone O-rings, silicone and ABS valve, and polydimethylsiloxane (silicone) lubricant.

The device is intended to be used in a hospital setting, with sterile medical supplies. The intended user of this device is a clinician who is performing an epidural procedure.

5 INTENDED USE

EpiZact is intended for use with an epidural needle for detecting a loss of resistance, which aids a clinician in verifying needle tip placement in the epidural space.

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE

Characteristics	EpiZact	EpiFaith	Differences
Indications for Use	Intended for use with an epidural needle for detecting a loss of resistance, which aids a clinician in verifying needle tip placement in the epidural space.	Intended for use with an epidural needle for detecting a loss of resistance, which aids a clinician in verifying needle tip placement in the epidural space.	Same
Patient Population	Not designed for the treatment of any specific disease or condition, nor does it have a target population.	Not designed for the treatment of any specific disease or condition, nor does it have a target population.	Same
Principle of operation	Loss of resistance (LOR)	Loss of resistance (LOR)	Same
Signal mechanism	A visual and tactile signal is triggered when the needle tip enters the epidural space, indicating a clear endpoint for the advancement of the needle.	A visual signal is triggered when the needle tip enters the epidural space, indicating a clear endpoint for the advancement of the needle.	Similar. EpiZact has tactile feedback in addition to visual feedback.
Nozzle type	Compatible with 16–18 gauge epidural needles. One model: Luer slip (as per ISO 80369-7)	Compatible with 16–18-gauge epidural needles. Two models (two colors): Luer slip (as per ISO80369-7) NRFit™ (as per ISO80369-6)	Luer slip connector (ISO 80369-7) is the same. NRFit™ connector (ISO 80369-6) is not part of this EpiZact application.
Materials	Plastic Components: Copolyester and ABS O-Ring/Seal/Valve: Silicone Springs: Stainless steel	Plastic Components: Polypropylene O-Ring/Seal: Synthetic and silicone rubber Spring: Stainless steel	Similar. The material differences between the subject and predicate devices do not alter suitability of the proposed device for its intended use. Materials were subject to a biocompatibility assessment per ISO 10993- 1.
Lubricant	Silicone oil	Silicone oil	Same
Biocompatibility	Biocompatibility Assessment meets ISO 10993-1.	Biocompatibility Assessment meets ISO 10993-1.	Same
Single use	Yes	Yes	Same

Characteristics	EpiZact	EpiFaith	Differences
Sterilization	E-beam radiation as per ISO 11137. Sterile assurance level: 10-6	E.O gas sterilization as per ISO 11135. Sterile assurance level: 10-6	Similar. Both sterilization methods are recognized as Established Category A sterilization methods. Sterilization methodology was verified through sterilization validation.
Performance standards	ISO 7886-1 ISO 80369-7 USP 788 particulates Operational Bench Tests	ISO 7886-1 ISO 80369-7 USP 788 particulates	Same, with additional bench tests performed on EpiZact.
Packaging	Tyvek and PET pouch with SBS backer card.	Tyvek and PET pouch.	Same, with additional SBS cardboard backer card in EpiZact packaging.

The subject device (EpiZact) has the same indications for use, use environment, patient population, and principle of operation as the predicate device (EpiFaith). Both the subject and predicate use the same lubricant and are single use. The nozzle type (Luer) is identical to one of the two models of the predicate. The technical characteristics that are not identical are as follows:

Signal Mechanism - EpiZact provides tactile feedback in addition to visual feedback when a loss of resistance is detected. The tactile feedback is also designed to help reduce the forward motion of the needle. This adds no new concerns for safety or efficacy, and ultimately adds a margin of safety by providing additional feedback to the user and reduced needle motion.

Materials - The plastic components of EpiFaith are made from polypropylene, whereas the plastic components of EpiZact are made from copolyester and ABS. All EpiZact materials are medical grade and of similar properties to the materials of EpiFaith. The entire EpiZact assembly was validated through a biocompatibility assessment per ISO 10993.

Sterilization - EpiZact is sterilized by E-beam. EpiFaith is sterilized by E.O. gas. Both methods of sterilization are "Established Category A" methods, with equivalent sterility assurance. The sterilization method for EpiZact was validated through sterilization verification testing per ISO 11137.

Performance Testing - EpiZact completed all the same performance tests as EpiFaith, with the addition of benchtop performance tests. These custom tests were added to assess operational performance of the device.

Packaging - EpiZact and EpiFaith both utilize Tyvek and PET (polyethylene terephthalate). EpiZact packaging contains an additional backer made from SBS (solid bleached sulfate). The packaging configuration for EpiZact was validated with distribution conditioning, environmental conditioning, and sterile package integrity. Biocompatibility testing conducted on packaged devices verify that this packaging presents no new concerns for safety.

7 PERFORMANCE DATA

The following tests were performed on EpiZact in support of the substantial equivalence determination:

Performance Tests

ISO 7886-1:2017 – Sterile hypodermic syringes for single use — Part 1: Syringes for manual use

- Section 6.1 – Extraneous Matter (Visual Inspection)
- Section 6.2, Annex A – Limits for Acidity
- Section 6.3, Annex A – Limits for Extractable Metals
- Section 7 – Lubricant (Visual Inspection)
- Section 12.2 – Position of Nozzle on End of Barrel (Visual Inspection)
- Section 12.3 – Nozzle Lumen (Visual Inspection)
- Section 13.2, Annex B – Freedom from Air Leakage Past Plunger Stopper
- Section 13.4 – Fit of Plunger/Stopper in Barrel

ISO 80369-7:2021 – Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

- Section 5 – Dimensioning
- Section 6.2, Annex D – Sub-Atmospheric Pressure Air Leakage
- Section 6.1.3, Annex C – Falling Drop Positive Pressure Liquid Leakage
- Section 6.4, Annex F – Resistance to Separation from Axial Load
- Section 6.5, Annex G – Resistance to Separation from Unscrewing
- Section 6.6, Annex H – Resistance to Overriding
- Section 6.3, Annex E – Stress Cracking

USP <788> – Particulate Matter in Injections

Biocompatibility Tests

ISO 10993-4:2017 – Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood

- Hemolysis Test

ISO 10993-5:2009 – Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

- Cytotoxicity Evaluation

ISO 10993-10:2021 – Biological evaluation of medical devices — Part 10: Tests for skin sensitization

- Dermal Sensitization

ISO 10993-11:2017 – Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

- Acute Systemic Toxicity

ISO 10993-23:2021 – Biological evaluation of medical devices — Part 23: Tests for irritation

- Intracutaneous Test

Sterile Barrier Package Testing

ASTM F1980-21 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D4332-14 – Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM D4169-22 – Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F2096-11 – Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak)
ASTM F88/F88M-15 – Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886/F1886M-16 – Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Sterilization Testing

ISO 11137-1:2006/(R)2015 & A1:2013 & A2:2019 – Device Sterilization
ISO 11137-2:2013/(R)2019 - Sterility Verification
ISO 11137-3:2017 - Dose Mapping
ISO 11737-1:2018 & A1:2021 – Bioburden
USP <85> – Bacterial Endotoxins

Performance Benchtop Testing

Production Benchtop Testing
Human Factors Studies

8 CONCLUSION

Testing conducted under performance, biocompatibility, sterile barrier packaging, and sterilization demonstrate the subject device is substantially equivalent to the predicate device. The differences between the devices do not raise any new questions of safety or effectiveness.

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well or better than the legally marketed predicate device.