K182268 510(k) Summary

1. Submitter

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2. Subject Device

Name of Device: EpiFaith Syringe (Luer Slip), EpiFaith Syringe (NRFit)
Common/Usual Name: Syringe, Piston
Device Classification: Class II
Classification Name: Piston Syringe
Regulation Number 21 CFR 880.5860
Product Code: FMF

3. Predicate Devices

Name of Device:	AutoDetect Syringe
Common/Usual Name:	Syringe, Piston
Device Classification:	Class II
Classification Name:	Piston Syringe
Regulation Number	21 CFR 880.5860
Product Code:	FMF
Premarket Notification	K041590

4. Device Description and technology Characteristics

The EpiFaith is a loss of resistance syringe with a spring-loaded piston, which can provide a means for detecting entry into the epidural space. Based on the principle of the LOR technique, the piston will simultaneously move forward when the pressure drop occurs due to the spring force. The moving of the piston can provide a visual signal to indicate the LOR as well as assist in verifying the needle tip placement in the epidural space. The EpiFaith syringe is compatible to a 16-18 gauge epidural needle with Luer or NRFit connector. The user can push the plunger to increase the pressure after the syringe is connected to an inserted needle. Then, the user can advance the needle until the visual signal occurs. Because the piston is spring loaded, the automatic ejection of the content of the syringe will happen when the LOR occurs, resulting in the movement of the piston. There are two different models of EpiFaith Syringe. The proposed models are listed in Table 4.1. The only differences between two models are the type of the connector and color.

Table 4.1: Proposed models of Flat Medical EpiFaith Syringe

Flat Medical EpiFaith Syringe	
Model #	**Connector type**
FM-01SLR	Luer slip
FM-02SNR	NRFit

5. Indications for Use

EpiFaith Syringe 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 the Predicate Device

ELEMENT OF COMPARISON	SUBJECT DEVICE	PREDICATE DEVICE
Trade name	EpiFaith Syringe	AutoDetect Syringe
510(k) number	K182268	K041590
Regulation Number	21 CFR 880.5860	21 CFR 880.5860
Regulation Name	Piston Syringe	Piston Syringe
Regulatory Class	II	II
Product Code	FMF	FMF
Syringe type	Piston Syringe	Piston Syringe
Intended use	EpiFaith Syringe 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.	The AutoDetect Syringe is intended for use with an epidural needle for the verification of needle tip placement in the epidural space.
Principle of operation	EpiFaith Syringe is based on the principle of LOR, loss of resistance	The AutoDetect Syringe is based on the principle of LOR, loss of resistance
Nozzle type	**There are two models.** Luer slip (follow ISO80369-7) NRFit (follow ISO80369-6)	-
Lubricant	Silicone oil	-
Reuse durability	Single use only	-
Material	Polypropylene natural & synthetic rubber The spring is made of stainless steel.	Polypropylene Silicone Polycarbonate
Biocompatibility	Meets guidelines presented in Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.	Meets guidelines presented in ISO 10993-1:2009.
Sterilization method	E.O gas sterilization Sterile assurance level : 10^{-6}	-
Dimensions	Length:103.0mm to 134.0mm	-

	Outer diameter of barrel:14.6mm Weight: 7.0g Maximum usable capacity:4ml	
Applicable standard	ISO 7886-1 ISO 80369-6 ISO 80369-7	ISO 7886-1
Packaging	Single device is contained in an E.O. gas permeable bag as the sterile barrier. The bag is made by Tyvek and PET with 200mm*75mm of dimension. Fifty bags are contained in a folding carton (205*175*160mm).	-

Substantial Equivalence

The subject device has the same intended use, technology, operation principle and the technical characteristics with the predicate device. Design Verification activities were performed on subject device and all tests were verified to meet the required acceptance criteria. The verification tests demonstrate that the differences in the device do not affect the intended use of the device. There are no significant differences between subject device and the predicate device(s) that would adversely affect the use of the product. We conclude that subject device is substantially equivalent to the predicate device.

7. Performance Data:

Non-Clinical Tests

Performance Data	FDA guidance and recognized consensus standards have been established for Piston Syringes under FDA Product Code FMF and 21 CFR 880.5860. A battery of tests was performed based on the requirements of the below recognized consensus standards and guidance, as well as biocompatibility, sterilization, and packaging standards and guidance. Conformity to these standards demonstrates that the proposed EpiFaith Syringe met the standards' established acceptance criteria for the device. ● ISO 7886-1:2017, Sterile hypodermic syringes for single use – Part 1: Syringes for manual use ● ISO 80369-6:2016, Small-bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications ● ISO 80369-7: 2016, Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
	● ISO 80369-20: 2015, Small-bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods ● ISO 10993-1, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process ● ISO 10993-4, Biological evaluation of medical devices— Part 4: Selection of tests for interactions with blood ● ISO 10993-5, Biological evaluation of medical devices— Part 5: Tests for in vitro cytotoxicity

Performance Data cont'd	• ISO 10993-7, Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals • 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 • ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices • 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 F1140, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages • ASTM F1608-00, Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method) • ISO 15223-1, Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements • ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials • USP <85>, Bacterial Endotoxins Test • USP <151>, Pyrogenicity Test • USP <161>, Medical Devices-Bacterial Endotoxin and Pyrogen Tests
Performance	

Data cont'd	● ISO 28590, Sampling procedure for inspection by attributes – Introduction to the ISO2859 series of standards for sampling for inspection by attributes ● ASTM F88, Standard Test Method for Seal Strength of Flexible Barrier Materials ● ASTM F1886, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection ● ASTM F1929, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration ● ISO 11737-2, Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process ● ISO 14971, Medical devices. Application of risk management to medical devices ● USP <788>, Particulate Matter in Injections
	Performance Bench Testing ● Visual indicator response time ● Needle protruding length and visual indicator activation on an epidural simulator ● Resistance of the O-ring ● Human Factors and Usability Testing on an epidural simulator The EpiFaith Syringe complies with the FDA recognized consensus standards: ● ISO 7886-1:2017

	● ISO 80369-6:2016 ● ISO 80369-7:2016, as outlined within this submission. Results of the testing demonstrate that the subject device met the acceptance criteria sufficient for its intended use.
	Biocompatibility testing The biocompatibility evaluation for the EpiFaith Syringe was conducted in accordance with the FDA Guidance Document "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process, June 16, 2016, and International Standard ISO 10993-1 "Biological Evaluation of Management Process," as recognized by FDA. Testing included the following: ● Hemolysis ● In vitro cytotoxicity ● Skin sensitization ● Intracutaneous irritation ● Acute systemic toxicity ● Material-Mediated Pyrogens ● Limulus amoebocyte lysate endotoxin The EpiFaith Syringe is considered tissue/bone/dentin contacting for a duration of less than 24 hours.

8. Conclusion

Based on the intended use, materials, design, and performance testing, the EpiFaith Syringe meets the requirements that are considered essential for its intended use and is considered substantially equivalent to the predicate device, the AutoDetect Syringe, K041590.