September 27, 2019

Flat Medical Co., Ltd
Shao Wei Tseng
Cheif of Regulatory Officer
9F-1., No27, Sec.1, Chang' An E. Rd.,
Zhongshan Dist., Taipei City 10441, Taiwan

Re: K192421
Trade/Device Name: EpiFaith Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 28, 2019
Received: September 4, 2019

Dear Shao Wei Tseng:

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); 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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192421

Device Name
EpiFaith Syringe (Luer Slip)
EpiFaith Syringe (NRFit)

Indications for Use *(Describe)*
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.

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.

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510(k) Summary

K192421

1. Submitter

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Flat Medical Co., Ltd.
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Date of Preparation August 28, 2019

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:	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
Premarket Notification	K182268

4. Device Description and technology Characteristics

The EpiFaith is a loss of resistance syringe with spring loaded piston, which can provide a means for detecting entry into the epidural space. Based on the principle of 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 verify 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 occurring. Because the piston is spring loaded, the automatic ejection of the content of the syringe will happen when the LOR occurring, resulting in the movement of the piston. There are two different models of EpiFaith Syringe. The proposed models are listed below. The only difference between two models is the type of the connector.

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

5. 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.

6. Comparison of Technological Characteristics with the Predicate Device

ELEMENT OF COMPARISON	SUBJECT DEVICE	CLAIM SUBSTANTIALLY EQUIVALENT DEVICE
Trade name	EpiFaith Syringe	EpiFaith Syringe
510(k) number	To be determined	K182268
Regulation Number	21 CFR 880.5860	
Regulation Name	Piston Syringe	
Regulatory Class	II	
Product Code	FMF	
Syringe type	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.	
Principle of operation	EpiFaith Syringe is based on the principle of LOR, loss of resistance	
Nozzle type	There are two models. Luer slip (follow ISO 80369-7) NRFit (follow ISO 80369-6)	
Lubricant	Silicone oil	
Reuse durability	Single use only	
Material	polypropylene **synthetic & silicone rubber** stainless steel.	polypropylene **synthetic & natural rubber** stainless steel.
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.	
Sterilization method	E.O gas sterilization Sterile assurance level : 10^{-6}	
Applicable standard	ISO 7886-1 ISO 80369-6 ISO 80369-7	
Packaging	Tyvek and PET	

This submission addressed a material change to the syringe piston. The indication for use, the principle of operation, and technological characteristics of the subject device are identical to the predicate device. The subject device is substantially equivalent to the predicate device.

7. Performance Data:

Non-Clinical Tests

We have conducted non-clinical testing based on its risk assessment utilizing Failure Mode Effect Analysis (FMEA). The following evaluations were conducted to validate the modifications made to the subject device:

- Risk assessment (ISO 14971: 2007)
- Friction forces test and liquid leakage test (ISO 7886-1: 2017)
- Biocompatibility Assessment per ISO 10993: In vitro cytotoxicity, Skin sensitization, Intracutaneous irritation, Acute systemic toxicity, Pyrogen test, Limulus amebocyte lysate endotoxin.

8. Conclusion

Based on the intended use, materials, design, biocompatibility testing and performance testing, the material change of syringe piston meets the requirements that are considered essential for its intended use and the subject device is considered substantially equivalent to the predicate device, the EpiFaith Syringe, cleared under K182268.

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 necessary tests were verified to meet the required acceptance criteria. The verification tests demonstrate that the differences in the material of syringe piston do not change the intended use of the device or raise different questions of safety and effectiveness. 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 predicate devices.