September 21, 2022

Flat Medical Co., Ltd.
Tseng Shao Wei
Chief of Regulatory Officer
9F.-1 No. 27, Sec. 1, Chang'an E. Rd.
Zhongshan Dist.
Taipei City, 10441
Taiwan

Re: K212615
Trade/Device Name: EpiFaith CV
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 16, 2022
Received: September 19, 2022

Dear Tseng Shao Wei:

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,

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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)*
K212615

Device Name
EpiFaith CV

Indications for Use *(Describe)*
The EpiFaith CV is intended for use in central venous catheter placement procedure, which is designed to facilitate guidewire-assisted catheter placement and is compatible with guidewires ranging from 0.025"(0.64mm) to 0.038"(0.96mm) along with their appropriate introducer needles. The device provides a visual cue when it hits a vessel with >50mmHg of pressure. The EpiFaith CV will be sold sterile individually packaged, and as part of a sterile kit. Neonates and infants shall be excluded from the intended population.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

## 1. Submitter

| | |
|---|---|
| **Name** | Flat Medical Co., Ltd. |
| **Address** | 9F.-1, No. 27, Sec. 1, Chang'an E. Rd., Zhongshan Dist., Taipei City 10441, Taiwan |
| **Contact Person** | Shao Wei, Tseng |
| **Title** | Chief of Regulatory Officer |
| **Email** | shaowei@flatmedical.com |
| **Telephone number** | +886-2-25672959#13 |
| Date of Preparation | March 25, 2022 |

## 2. Subject Device

| | |
|---|---|
| **Name of Device** | EpiFaith CV |
| **Device Classification** | Class II |
| **Classification Name** | Catheter guide wire |
| **Regulation Medical Specialty** | Cardiovascular |
| **Regulation Number** | 21 CFR 870.1330 |
| **Product Code:** | DQX |

## 3. Predicate Devices and reference device

| | Predicate device |
|---|---|
| **Name of Device** | Introducer Safety Syringe |
| **Common/Usual Name** | Wire, Guide, Catheter |
| **Device Classification** | Class II |
| **Classification Name** | Catheter guide wire |
| **Regulation Number** | 21 CFR 870.1330 |
| **Product Code** | DQX |
| **Premarket Notification** | K884490 |

| | Reference device |
|---|---|
| **Name of Device** | EpiFaith Syringe (Luer), 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** | K192421 |

## 4. Device Description and technology Characteristics

The EpiFaith CV is a syringe with spring loaded piston, which can provide a high/low blood pressure signal when introducer needle tip entry to the blood vessel. Based on the principle of blood pressure differences in different blood vessel, the piston will simultaneously move backward when the pressure increase occurs due to the high blood pressure in the syringe barrel. The moving of the piston can provide a visual signal to indicate the high/low blood pressure as well as verify the introducer needle tip placement in the blood vessel.

## 5. Intended Use

The EpiFaith CV is intended for use in central venous catheter placement procedure, which is designed to facilitate guidewire-assisted catheter placement and is compatible with guidewires ranging from 0.025" (0.64mm) to 0.038" (0.96mm) along with their appropriate introducer needles. The device provides a visual cue when it hits a vessel with>50mmHg of pressure.

The EpiFaith CV will be sold sterile individually packaged, and as part of a sterile kit. Neonates and infants shall be excluded from the intended population.

## 6. Comparison of Technological Characteristics with the Predicate Device and Reference Device

| | **Subject device**<br>EpiFaith CV | **Predicate Device**<br>Introducer Safety Syringe<br>(K884490) | **Reference device**<br>EpiFaith Syringe<br>(K192421) |
|---|---|---|---|
| **Intended Use** | The EpiFaith CV is intended for use in central venous catheter placement procedure, which is designed to facilitate guidewire-assisted catheter placement and is compatible with guidewires ranging from 0.025" (0.64mm) to 0.038" (0.96mm) along with their appropriate introducer needles. The device provides a visual cue when it hits a vessel with>50mmHg of pressure. The EpiFaith CV will be sold sterile individually packaged, and as part of a sterile kit. Neonates and infants shall be excluded from the intended population. | The Arrow Raulerson Syringe is indicated for use with spring-wire guides ranging from .025" (.64 mm) to .038" (.96 mm) and spring-wire guide introduction needles sized to place these wires. The syringe allows for vessel location and passage of the guidewire through the syringe obviating the need for separating the introducer needle from the syringe. | 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. |
| **Applicable Guidewire range** | 0.025" (0.64mm) to 0.038" (0.96mm) | 0.025" (0.64mm) to 0.038" (0.96mm) | N/A |
| **Connectivity** | Luer (ISO 80369-7) | Luer | Luer (ISO 80369-7)<br>NRFit (ISO 80369-6) |
| **Nozzle type** | Single Use | Single Use | Single Use |
| **Material** | Plastic materials<br>Stainless steel<br>Elastomer | Plastic materials<br>Stainless steel<br>Elastomer | Polypropylene<br>Synthetic & silicone rubber<br>Stainless steel. |
| **Lubricant** | Silicone oil | - | Silicone oil |
| **Biocompatibility** | ISO 10993-1 | ISO 10993-1 | ISO 10993-1 |
| **Sterilization method** | E.O gas sterilization<br>Sterile assurance level: $10^{-6}$ | E.O gas sterilization | E.O gas sterilization<br>Sterile assurance level: $10^{-6}$ |
| **Packaging** | Individually packaged or as part of a kit. | Individually packaged or as part of a kit. | Individually packaged in a Tyvek pouch |

## 7. Performance Data:

### Non- Clinical Tests

| Biocompatibility test | | |
|---|---|---|
| **Test** | **Standard** | **Results** |
| Cytotoxicity | ISO 10993-5:2009 | Pass |
| Sensitization | ISO 10993-10:2010 | Pass |
| Irritation or intracutaneous reactivity | ISO 10993-10:2010 | Pass |
| Acute systemic toxicity | ISO 10993-11:2017 | Pass |
| Material-medicated pyrogenicity | USP <151> | Pass |
| Hemocompatibility | ISO 10993-4:2017 & ASTM F756 | Pass |
| Endotoxin | USP <85> & USP <43> | Pass |
| **Sterilization** | | |
| **Test** | **Standard** | **Results** |
| Sterilization validation | ISO 11135:2014 | Pass |
| Sterility test | ISO 11737-2:2019 | |
| Bioburden & Recovery test | ISO 11737-1:2018 | |
| EO residue | ISO 10993-7:2008 | |
| **Shelf life and performance bench test** | | |
| **Test** | **Standard** | **Results** |
| Seal strength test | ASTM F88 | Pass |
| Bubble leak test | ASTM F2096 | Pass |
| Sterility test | ISO 11737-2:2019 | Pass |
| Negative pressure leakage | Flat Medical internal protocol | Pass |
| Positive pressure leakage | Flat Medical internal protocol | Pass |
| Auto-aspirating mechanism | Flat Medical internal protocol | Pass |
| Positive pressure indication | Flat Medical internal protocol | Pass |
| Resistance of passing guidewire | Flat Medical internal protocol | Pass |
| Fatigue tests of latches | Flat Medical internal protocol | Pass |
| Fluid leakage – Positive pressure liquid leakage | ISO 80369-7:2016 & ISO 80369-20:2015 | Pass |
| Sub- atmospheric pressure air leakage | ISO 80369-7:2016 & ISO 80369-20:2015 | Pass |
| Stress cracking | ISO 80369-7:2016 & ISO 80369-20:2015 | Pass |
| Resistance to separation from axial load | ISO 80369-7:2016 & ISO 80369-20:2015 | Pass |

### Clinical Tests

The submission does not contain clinical data. Product functionality has been adequately assessed by non-clinical tests.

### Animal Tests

The submission does not contain animal testing data.

## 8. Conclusion

Based on the intended use, materials, design, and performance testing, the EpiFaith CV meets the requirements that are considered essential for its intended use and is considered substantially equivalent to the predicate device, the Introducer Safety Syringe, K884490.

### Substantial Equivalence

The subject device has same intended use, technology, operation principle and 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 or raise any unsolved issues. There is no significant difference between subject device and the predicate device that would adversely affect the use of the product. We conclude that subject device is substantially equivalent to predicate devices.