October 31, 2023

Medovate Limited
% Pamela Papineau
Delphi Medical Device Consulting, Inc.
5 Whitcomb Ave
Ayer, Massachusetts 01432

Re: K230083
Trade/Device Name: Safira
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: FRN
Dated: September 29, 2023
Received: September 29, 2023

Dear Pamela Papineau:

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,

Jake K. Lindstrom -S

Digitally signed by Jake K. Lindstrom -S
Date: 2023.10.31 16:23:58 -04'00'

Jake Lindstrom, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
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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)*
K230083

Device Name
SAFIRA

Indications for Use *(Describe)*
The Medovate SAFIRA system is intended for use by trained clinicians to administer local anaesthetic below a specified pressure threshold to a target nerve bundle for regional anaesthesia.

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 General Information

Owners Name	Medovate Limited The Workplace, Camboro Business Park Girton, Cambridge, CB3 0QH
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Date Prepared:	October 30, 2023
Device Trade Name:	SAFIRA
Common/Usual Name:	Infusion Pump
Product Code:	FRN
Classification Name:	Infusion Pump
Device Regulation	21 CFR 880.5725
Device Classification	Class II

Predicate Device:	Medovate Limited SAFIRA; K153599
Common/Usual Name:	Infusion Pump
Product Code:	FRN
Classification Name:	Infusion Pump
Device Regulation	21 CFR 880.5725
Device Classification	Class II

1.1 Indications for Use:

The Medovate SAFIRA system is intended for use by trained clinicians to administer local anaesthetic below a specified pressure threshold to a target nerve bundle for regional anaesthesia.

1.2 Device Description:

The Medovate SAFIRA device is an infiltration pump used to infuse local anesthetic drugs into the body as part of a Regional Anaesthesia procedure.

The SAFIRA device consists of a sterile, single-use plastic Syringe (20mL capacity) fitted with a custom collar and plunger, a non-sterile reusable Driver, and a non-sterile reusable Operator. SAFIRA is a battery powered motorized syringe driver for use in delivering anaesthetic via injection during a Peripheral Nerve Block (PNB) Procedure.

The user fills the syringe with the fluid of choice, then locks the filled Syringe into the Driver, where the specially designed Syringe Plunger rack mates with the Driver Gear. When the SAFIRA Syringe is attached to the Driver, the collar locks the Syringe to the Driver housing, and the Plunger engages with the Driver Gear to advance or retract the Syringe Plunger.

The female Luer or NRFit connection of a sterile, single-use needle set (not supplied by Medovate) is attached to the standard male Luer or NRFit fitting on the SAFIRA Syringe. The Operator (Foot Pedal or Palm Operator) connector is plugged into the receptacle on the Driver, ready for use.

The Driver contains non-replaceable AAA batteries which power a small DC motor which in turn controls the movement of the Syringe Plunger.

The Operator consists of 2 color-coded controls; when the user applies pressure to the appropriate control (green = infuse, yellow = aspirate), the motor activates the Plunger movement mechanism to move the Plunger forwards (infuse/inject) or backwards (aspirate).

The Driver is designed to deliver fluid at a maximum flow rate of 0.5mL/sec. The motor is designed with an overpressure safety feature, which causes the Plunger movement to stop if the pressure in the syringe exceeds 17psi ±3psi regardless of whether the “infuse” control of the operator is depressed.

1.3 Substantial Equivalence:

The proposed SAFIRA device described in this 510(k) is substantially equivalent to the predicate SAFIRA device cleared in 510(k) K153599.

Substantial equivalence has been demonstrated by following the FDA Guidance: "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", and accompanying text in the guidance.

The following table demonstrates a summary of the Substantial Equivalence between the Predicate Unmodified SAFIRA device (cleared in 510(k) K153599), and the proposed SAFIRA device.

Table 1: General Substantial Equivalence Comparison

Criteria	**Predicate Device: Unmodified SAFIRA** (As per 510(k) K153599)	**Proposed Device: SAFIRA** (K230083)	**Comments**
Regulatory Equivalence			
FDA Classification Name	Infusion Pump	Infusion Pump	Identical
Product Code	FRN	FRN	Identical
Regulation	21 CFR 880.5725	21 CFR 880.5725	Identical
Device Class	II	II	Identical
Classification Panel	General Hospital Devices	General Hospital Devices	Identical
Common / Usual Name	Infiltration Pump	Infiltration Pump	Identical
Manufacturer	Medovate Ltd	Medovate Ltd	Identical
Intended Operator	Physician or another qualified medical professional	Physician or another qualified medical professional	Identical

Criteria	Predicate Device: Unmodified SAFIRA (As per 510(k) K153599)	Proposed Device: SAFIRA (K230083)	Comments
Intended Use	Syringe infusion pump operated via a foot pedal for the infusion of non-IV fluids into the body.	Syringe infusion pump operated via an operator for the infusion of non-IV fluids into the body.	Substantially Equivalent The wording "Foot Pedal" has been replaced by "Operator" as the SAFIRA Palm Operator has been added to the proposed SAFIRA device. The principle of operation, indications for use and intended purpose remain unchanged.
Contraindicated for IV Fluid Delivery	Yes	Yes	Identical
Indications for Use	The Concert Medical Hands-Free Syringe is indicated for general fluid irrigation / infiltration.	The Medovate SAFIRA System is intended for use by trained clinicians to administer local anaesthetics below a specified pressure threshold to a target nerve bundle for regional anaesthesia.	Substantially Equivalent The wording of the proposed SAFIRA device has been amended to be more specific and provide an Indication for Use which is in line with the use of the device. The use of the proposed SAFIRA remains unchanged from the predicate unmodified SAFIRA device, and both devices have the same medical intention.

Criteria	**Predicate Device: Unmodified SAFIRA** (As per 510(k) K153599)	**Proposed Device: SAFIRA** (K230083)	**Comments**
Design and Technology Equivalence			
Sterile Device?	Sterile: Syringe Non-Sterile: Driver Operator	Sterile: Syringes Non-Sterile: Driver Operators	Identical
Single Use Device?	Single Use: Syringe Reusable: Driver Operator	Single Use: Syringes Reusable: Driver Operators	Identical
Fundamental Scientific Technology	Non-IV fluids infused into the body via a needle/cannula through the application of pressure exerted on the syringe plunger through motor-driven motion.	Local anaesthetic fluids infused into the body via a needle/cannula through the application of pressure exerted on the syringe plunger through motor-driven motion.	Equivalent SAFIRA has restricted its use to Local Anesthetic in line with its Indications for Use. The Fundamental Technology of the predicate unmodified and proposed SAFIRA devices remains unchanged.
Pump Type	Piston-Driven Syringe	Piston-Driven Syringe	Identical
Infusion Fluid Reservoir	Syringe (20ml), filled by user	Syringe (20ml), filled by user	Identical

Criteria	Predicate Device: Unmodified SAFIRA (As per 510(k) K153599)	Proposed Device: SAFIRA (K230083)	Comments
Compatible Needle Sets	B. Braun Stimuplex A 22G x 2” B. Braun Ultra 22G x 3-1/8” Pajunk Sonoflex Stim 22G x 50mm Life-Tech EchoBright 22G x 50mm	Needle Gauge: >22G Needle Length: <120mm	Minor Difference The unmodified predicate SAFIRA device limited its use to 4 specific regional nerve block needles. The proposed SAFIRA device limits use to a range of needle sizes which include the previously specified needles.
Power Source	Battery	Battery	Identical
Materials			
Fluid Path Materials	Syringe Body: Polypropylene	Syringe Body: Polypropylene	Identical
	Syringe Body Lubricant: Silicone oil	Syringe Body Lubricant: Silicone oil	
	Seal: Isoprene Synthetic rubber	Seal: Isoprene Synthetic rubber	
	Note: Materials are identical to those contained in the Dragon Heart Medical Devices syringes cleared in K042547	Note: Materials are identical to those contained in the Dragon Heart Medical Devices syringes cleared in K042547	

Criteria	Predicate Device: Unmodified SAFIRA (As per 510(k) K153599)	Proposed Device: SAFIRA (K230083)	Comments
Performance Equivalence			
Maximum Infusion Flow Rate	0.5ml/sec (30mL/min) using 22G needle set	0.5ml/sec (30ml/min) using compatible needle set	Identical
Maximum Infusion Pressure	13psi (±2psi)	17psi (±3psi)	Difference to predicate. The pressure limit has been increased, however there is no impact on safety and no new risks have been introduced.
User Interface Equivalence			
User Interface	User fills the sterile syringe with infusion fluid, places the syringe in the pump mechanism (Driver), attaches the sterile infusion tubing and needle (not provided by Medovate) and attaches the Foot Pedal to the pump mechanism. User initiates fluid infusion or aspiration by pressing on the Foot Pedal.	User fills the sterile syringe with local anaesthetic, places the Syringe in the pump mechanism (Driver), attaches the sterile infusion tubing and needle (not provided by Medovate) and attaches the Operator to the pump mechanism. User initiates fluid infusion or aspiration by pressing on the Operator control.	Difference to predicate. 'Foot Pedal' replaced by 'Operator' due to the additional Palm Operator variant which has been added to the proposed SAFIRA device. The principle of operation remains the same.

Criteria	Predicate Device: Unmodified SAFIRA (As per 510(k) K153599)	Proposed Device: SAFIRA (K230083)	Comments
Syringe Connection	Luer Syringe (ISO 80369-7)	Luer Syringe (ISO 80369-7) NRFit Syringe (ISO 80369-6)	Minor Difference to Predicate An NRFit Syringe has been developed and added to the proposed SAFIRA device. The introduction of the NRFit Syringe to the SAFIRA device has not affected device use and allows the user / facility to choose a syringe to match the needle type they already use for regional blocks.

1.4 Non-Clinical Performance Testing:

Performance data demonstrated that SAFIRA has met the pre-determined acceptance criteria and is substantially equivalent to the predicate SAFIRA device. The risks associated with the proposed SAFIRA device were found to be acceptable when evaluated in accordance with ISO 14971:2019.

Performance testing included in this 510(k) application consists of system verification testing to verify the changes made to the SAFIRA device, including the injection pressure limit, inclusion of the NRFit Syringe and Palm Operator. This 510(k) submission includes an Infusion Pump Safety Case and the results of a Human Factors Study to validate the above changes.

1.5 Conclusion:

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The SAFIRA is substantially equivalent to the predicate unmodified SAFIRA cleared under K153599 with respect to the indications for use, target populations, treatment method, and technological characteristics.