April 16, 2023

Omeq Medical Ltd.
% Janice Hogan
Partner
Hogan Lovells, US LLP
1735 Market Street, 23RD Floor
Philadelphia, Pennsylvania 19103

Re: K221974
Trade/Device Name: EpiFinder
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: March 17, 2023
Received: March 17, 2023

Dear Janice Hogan:

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,

James J. Lee -S

James J. Lee, Ph.D.
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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K221974

Device Name

EpiFinder™

Indications for Use *(Describe)*

The EpiFinder is intended for use, in between a luer Loss of resistance (LOR) syringe and an epidural needle, to verify the needle tip placement in the epidural space as a secondary indicator adjunctive to the LOR technique.

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
Omeq Medical's EpiFinder™ – K221974

510k Owner:	Omeq Medical Ltd.
Address	17 Tchelet (sky) St. Misgav Business Park M.P. Misgav 2017400, Israel
Contact person:	Lior Margalit Omeq Medical Ltd. Bezalel 4, Ramat Gan, Israel (5252104) TEL: +972-(0)54-4315340 Email: lior@omeqmedical.com
Date Prepared:	April 13, 2023
Device Trade Name:	EpiFinder™
Common or Usual Name:	Loss of Resistance (LOR) Device
Classification:	Class II per 21 C.F.R. § 880.5860, *Piston Syringe*
Product Code:	FMF
Predicate Device:	Exmoor Plastics Limited's Epidrum (K093863)
Reference Device	Mirador Biomedical, Inc.'s Compass Epidural Assist (K112203)

A. INTENDED USE/INDICATION FOR USE

The EpiFinder is intended for use, in between a luer Loss of resistance (LOR) syringe and an epidural needle, to verify the needle tip placement in the epidural space as a secondary indicator adjunctive to the LOR technique.

B. DEVICE DESCRIPTION

The EpiFinder is intended to be used in conjunction with a standard epidural LOR technique as an independent secondary confirmatory indicator, giving the practitioner a clear visual signal that the needle tip has entered the epidural space. The EpiFinder is a sterile, single-use device that is used during epidural procedures. The device works with a standard loss of resistance (LOR) syringe and an epidural needle (18G) to verify that the needle tip placement is in the epidural space in patients ages 18 or older.

The EpiFinder consists of a blunt tip spring-loaded probe that is installed into a standard epidural needle, and a plastic housing that is composed of a linear actuator, a sensor, and a microcontroller that measures the probe spring's contraction. The EpiFinder is attached to a Tuohy needle that has been inserted into the patient. The device has built in "wings" to help advance the needle, if the practitioner wishes to use them. As the needle advances forward, there are LED indicator lights on the housing that give feedback to the operator as to when the epidural space is entered, as input to the user in conjunction with the standard LOR technique.

C. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Both the subject and predicate devices operate in conjunction with a standard luer LOR syringe and epidural needle to enable detection of when the needle has entered the epidural space. Both devices detect entry into the epidural space via tissue resistance differentiation, which is based on the well-known and widely used loss of resistance technique. In addition, both are comprised entirely or largely of medical-grade polymers.

The primary technological difference between the subject and predicate devices is that the predicate device incorporates an expandable membrane which deflates while the needle tip enters the epidural space and does not enable utilization of loss of resistance (LOR) technique by using the syringe, (though the reference device does). In contrast, the subject device enables a standard LOR technique (primary indicator) and a secondary indicator that uses a spring-loaded probe which expands while the needle tip enters the epidural space. The subject device provides a secondary indicator as to when the epidural space is entered while the predicate device replaces the LOR technique with its own indicator (membrane deflation).

A table comparing the key features of the subject, predicate, and reference devices is provided below.

Substantial Equivalence Table

Characteristic	**EpiFinder** (Subject device)	**Epidrum** (predicate device) (K093863)	**Compass Epidural Assist** (reference device) (K112203)
Classification	(Primary) 21 C.F.R. § 880.5860, *Piston Syringe* (Product Code FMF); (Secondary) 21 C.F.R. § 870.2850, *Transducer, BloodPressure, Extravascular* (Product Code DRS)	21 C.F.R. § 880.5860, *Piston Syringe* (Product Code FMF)	(Primary) 21 C.F.R. § 870.2850, *Transducer, BloodPressure, Extravascular* (Product Code DRS) (Secondary) 21 C.F.R. § 870.1435, *Computer, Diagnostic, Pre-Programmed, Single-Function* (Product Code DXG)
Intended use / Indications for Use	The EpiFinder is intended for use, in between a luer Loss of resistance syringe and an epidural needle, to verify the needle tip placement in the epidural space as a secondary indicator adjunctive to the LOR technique.	Intended Use: The Epidrum is intended for use in epidural procedures between a luer syringe and an epidural needle to give a clear visual signal that the needle tip has entered the epidural space. Indications for Use: The Epidrum is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space.	The Compass Epidural Assist disposable pressure transducer with integrated digital display is intended for direct measurement of physiological pressure.
Intended patient population	18 years of age and older	Adults	Information not available

Characteristic	**EpiFinder** (Subject device)	**Epidrum** (predicate device) (K093863)	**Compass Epidural Assist** (reference device) (K112203)
Single /multi use	Single Use	Single Use	Single Use
Rx / OTC	Rx	Rx	Rx
Shelf life	12 months	Information not available	Information not available
Sterility method	EtO sterile	EtO sterile	sterile
Enabling the operator utilize manual LOR technique by using a syringe	Enabled	Not enabled *The loss of resistance is indicated by the deflated membrane	Enabled
Principle of operation	The Epifinder is attached between a standard 18 G epidural needle and a LOR syringe to allow a standard LOR technique (Primary indicator) and simultaneously a secondary indicator the uses a spring-loaded probe that is compressed or expands in accordance to the resistance at the needle tip.	A small chamber, featuring an expandable membrane, which deflates as the needle tip enters the epidural space.	The compass is attached distally to an inserted needle / catheter to measure pressure via an embedded pressure sensor.
Sensing Technology	Force acting on spring loaded probe	Pressure acting on extendable membrane	Pressure acting on pressure transducer
Indicator of change (Display type)	LEDs	Subjective visual indication (membrane)	LCD
Attachment mechanism	Attached to standard epidural needle and syringe	Attached to standard epidural needle and syringe	Attached to standard epidural needle and syringe
Epidural Needle Size Compatibility	18G	16G-18G	Information not available
Source of Energy	Battery	Mechanical device	Battery
Software	Pre-programmed software (firmware)	Mechanical device	Pre-programmed software (firmware)
Materials	Medical grade polymers and medical grade stainless steel	Unidentified medical grade polymer(s) with a silicone diaphragm	Unidentified medical grade polymer(s)

D. PERFORMANCE DATA

Final verification/validation testing of the EpiFinder device is summarized below. The results were supportive of the device's safety and effectiveness for the proposed indications.

- Biocompatibility: Testing per ISO 10993 evaluated the relevant endpoints for an externally communicating device with limited contact with tissue: cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity and material-mediated pyrogenicity. All results were acceptable.

- Benchtop tests: LOR channel sealing integrity, LOR channel sealing integrity per ISO 80369-7, Luer dimensional and functional attributes verification, probe penetration force, probe integrity, sensing mechanism, wings mechanism, particulate matter, corrosion resistance, device integrity, device operation time under load, torques on Front Luer and Housing interface point, Sensing mechanism consistency throughout shelf-life and LOR channel resistance.

- Electrical Safety and Electromagnetic Compatibility (EMC): The EpiFinder was determined to be in conformance with IEC 60601 and other applicable standards for electrical safety and EMC.

- Software: Software verification and validation testing was conducted, and results were found acceptable for software release per IEC 62304:2006+AMD1:2015 and FDA's 2005 guidance document.

- Animal Study: A study in pigs was conducted to evaluate the safety and effectiveness of using the EpiFinder device in epidural procedures in accordance with the proposed indications for use. The study was conducted in compliance with the OECD principles of Good Laboratory Practice (GLP) ENV/MC/CHEM (98)17 (except for the blood analysis). The study evaluated numerous test sites which were randomly divided into two groups: Group 1 (where the EpiFinder was used in conjunction with standard LOR technique) and Group 2 (where standard LOR technique alone was used). Needle advancement was halted when the epidural space was identified either by the EpiFinder's LEDs or by standard LOR technique, and the finding was confirmed using X-ray and contrast medium (if needed). Results demonstrated that the device is appropriate for its intended use (only one adverse event) and effective in providing a clear visual signal that the epidural needle had entered the epidural space.

- Human Factors Evaluation: Usability studies have been conducted with the EpiFinder per IEC 62366-1:2015 and FDA's corresponding 2016 guidance document. The study was conducted with 16 anesthesiologists (physicians) and 10 student resident nurse anesthetists (sRNAs) to evaluate the safe use, any usability concerns, and clear readability of the IFU/labeling of the Epifinder. No use-related hazards were recorded. Three participants in each group experiences use problems, but these were deemed not to pose any additional risk. Additionally, users reported a high level of satisfaction with the device's design and ergonomic attributes.

- Clinical Evaluation: The EpiFinder was evaluated in a single arm, open label multicenter trial. The purpose of the trial was to assess the safety and performance of the EpiFinder in 31 adult subjects with clinical indication for a lumbar epidural steroid injection. The EpiFinder was found to be appropriate for use in human subjects. The performance of the device was also established, demonstrating that the device is capable of correctly identifying the epidural space during the injection procedure. In addition, the data from this trial demonstrate that the utilization of LOR technique with the EpiFinder is similar to the standard practice and that the device can be incorporated into clinical practice. All injections were performed on the lumbar region (21 injections in the L5-S1 interspace, 9 injections in the L4-L5 and one injection in L2-L3) while patients were in the prone position. 2 users conducted LOR technique with air as the medium while 1 user conducted it with saline as the medium.

E. CONCLUSION

The EpiFinder is as safe and effective as the Epidrum predicate device (K093863). The EpiFinder has the same intended use and similar indications for use, and technological characteristics and principles of operation, as the predicate device. The minor technological differences between the EpiFinder and its predicate device raise no new issues of safety or effectiveness, and the reference device – Compass Epidural Assist (K112203) – further supports these elements of the EpiFinder technology. Performance data demonstrate that the minor technological differences do not adversely impact the subject device's performance as intended. Thus, the EpiFinder is substantially equivalent.