June 16, 2023

Laurane Medical SAS

Mr. Laurent Fumex
Head of Company
Chemin de la bayette
ZAC de la bayette
Le Pradet, 83220
France

Re: K230015
Trade/Device Name: OmniBone™ Bone Marrow Biopsy Kit with Power Driver, OmniBone™ Bone Biopsy Kit with Power Driver

Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: May 4, 2023
Received: May 8, 2023

Dear Mr. Fumex:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.16 08:22:14 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control 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)*
K230015

Device Name
- Omnibone™ Bone Marrow Biopsy Kit with Power Driver
- Omnibone™ Bone Biopsy Kit with Power Driver

Indications for Use *(Describe)*
The Omnibone™ Bone Marrow Biopsy Kit is indicated for bone marrow aspiration and biopsy of the anterior or the posterior iliac crest of adult patients.
The Omnibone™ Bone Biopsy Kit is indicated for bone biopsy of the vertebral body and bone lesions.

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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K230015

Laurane Medical SAS
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France

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based as follows:

1. **Submitter Information:**

Applicant: Laurane Medical SAS
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ZAC de la Bayette
Le Pradet 83220 - FRANCE

Phone : 860-399-9900
Fax : 860-399-9200
Contact : Laurent Fumex
lfumex@lauranemedical.com;Laurane.medical@wanadoo.fr

Date : 3 January 2023

2. **Subject Device Name :**

Device Trade Name :	OmniBone™ Bone Marrow Biopsy Kit with Power Driver OmniBone™ Bone Biopsy Kit with Power Driver
Common Name:	Bone Marrow Biopsy Kit Bone Biopsy Kit
Classification:	Class II KNW (Gastroenterology – urology biopsy instrument)
Review Panel:	Gastroenterology / Urology
Regulation Number:	21 CFR 876.1075

3. Predicate Device

Device Trade Name:	OnControl™ Bone Access and Bone Biopsy System by Vidacare® OnControl™ Bone Marrow Biopsy System by Vidacare®
510(k) Number:	K113872, K142377
Common/Usual Name:	Cement Dispenser Conduit for Vertebroplasty and Bone Biopsy Needle, Bone Marrow Biopsy Needle
Classification:	Class II KNW (Gastroenterology – Urology biopsy instrument)
Regulation number:	21 CFR 876.1075

4. Subject Indications for Use:

The OmniBone™ Bone Biopsy Kit with Power Driver is indicated for bone biopsy of the vertebral body and bone lesions.

The OmniBone™ Bone Marrow Biopsy kit with Power Driver is indicated for bone marrow aspiration and biopsy of the anterior or the posterior iliac crest of adult patients.

5. Subject Device Description

The OmniBone™ Powered Biopsy System consists of a rechargeable Power Driver with Charger and compatible Biopsy Kits with Power Driver Pouch.

The OmniBone™ Bone Biopsy Kit with Power Driver Pouch and the OmniBone™ Bone Marrow Biopsy Kit with Power Driver Pouch are both provided sterile (EtO), are both single-use and are both designed exclusively for use with the OmniBone™ Power Driver. All OmniBone™ Biopsy Kits are available in different needle gauge sizes and lengths.

The OmniBone™ Power Driver with Charger is a handheld, Lith-on battery powered, and rechargeable Power Driver, reusable and supplied non-sterile .

The OmniBone™ Power Driver has a 3-position switch that controls the motion of the driver: reverse (counter clockwise) – off – forward (clockwise). The OmniBone™ Power Driver has a variable speed trigger that controls the speed of the driver. Applying light pressure on the trigger activates the driver at low speed and increasing the trigger pressure activates higher speeds. Full pressure on the trigger will activate full speed. No pressure on the trigger will stop the motor function. A charging LED indicator indicates the level of charge of the battery of the OmniBone™ Power Driver. An integrated connector allows the OmniBone™ Power Driver to connect to the OmniBone™ Charger.

6. Technological Comparison to Predicate Device

The table below provides a technological comparison between the subject device and the predicate device.

Characteristic		**Predicate** **OnControl™ Powered Bone Access System** OnControl™ Bone Marrow Biopsy System - K142377 OnControl™ Bone Access and Bone Biopsy System - K113872	**Subject** **OmniBone™ Powered Biopsy System** OmniBone™ Bone Marrow Biopsy kit with Power Driver OmniBone™ Bone Biopsy kit with Power Driver
Regulation Number		21 CFR 876.1075	21 CFR 876.1075
Class		II	II
Primary FDA Product Code		KNW - Instrument, Biopsy FCG - Biopsy Needle	KNW – Instrument, Biopsy
Indications for Use	Bone Marrow	The OnControl™ Bone Marrow Biopsy System is intended for bone marrow aspiration and biopsy in adult and pediatric patients age 2 and older.	The OmniBone™ bone marrow biopsy kit is indicated for bone marrow aspiration and biopsy of the anterior or the posterior iliac crest of adult patients.
	Bone Lesion	The OnControl™ Bone Access and Bone Biopsy System is intended for use with a standard cement delivery system for the fixation of fractures of the vertebral body using vertebroplasty and/or for bone biopsy of the vertebral body and bone lesions.	The OmniBone™ Bone Biopsy Kit with Power Driver is intended for bone biopsy of the vertebral body and bone lesions.

Characteristic		Predicate **OnControl™ Powered Bone Access System** OnControl™ Bone Marrow Biopsy System - K142377 OnControl™ Bone Access and Bone Biopsy System - K113872	Subject **OmniBone™ Powered Biopsy System** OmniBone™ Bone Marrow Biopsy kit with Power Driver OmniBone™ Bone Biopsy kit with Power Driver
Target Population	Bone Marrow	Adult and pediatric patients needing bone marrow aspiration or bone marrow biopsy.	Adult patients needing bone marrow aspiration or bone marrow biopsy.
	Bone Lesion	Patients requiring fixation of fractures of the vertebral body or bone biopsy.	Patients requiring bone biopsy.
Fundamental Scientific Technology		Power Driver with Needle Attachments	Power Driver with Needle Attachments
Power Driver Design		Cordless, lithium battery-powered; reusable with disposable sterile sleeve	Cordless, lithium battery-powered; reusable with disposable sterile sleeve
Power Driver Energy Delivered		Non rechargeable, Internal, 18 V Lithium Battery	Rechargeable, Internal, 4.2 V Lithium Battery
Power Driver Cybersecurity/Interfaces		Does not contain any external wired and/or wired communication interfaces	Does not contain any external wired and/or wired communication interfaces
Charger		No charger	Charger for power driver with DC power plug
Needle Design		Sterile, single-use, disposable	Sterile, single-use, disposable
Operating Principle		Needle set attaches to battery powered driver	Needle set attaches to battery powered driver
Mode of Action		Single puncture, bone access, and sample	Single puncture, bone access, and sample
Energy Used / Delivered		Lithium battery provides rotational kinetic energy to aid the physician in inserting and advancing the needle through cortical and/or cancellous bone	Lithium-on battery provides rotational kinetic energy to aid the physician in inserting and advancing the needle through cortical and/or cancellous bone
Imaging Compatibility		X-Ray / CT and Ultrasound Compatibility	X-Ray / CT and Ultrasound Compatibility

Characteristic		Predicate **OnControl™ Powered Bone Access System** OnControl™ Bone Marrow Biopsy System - K142377 OnControl™ Bone Access and Bone Biopsy System - K113872	Subject **OmniBone™ Powered Biopsy System** OmniBone™ Bone Marrow Biopsy Kit with Power Driver OmniBone™ Bone Biopsy Kit with Power Driver
Speed		Single-Speed	Variable
Power Driver Motion		Forward motion	Reverse and forward motion
Kit Components	Bone Marrow	OnControl™ Bone Marrow Biopsy Tray - Alignment Guide - Biopsy Needle - Depth Stop - Ejector Rod - Connector Hub with Sterile Sleeve - Fenestrated Drape	OmniBone™ Bone Marrow Biopsy Kit with Power Driver Pouch • Needle set: - Biopsy Cannula and Stylet with depth gauge (Biopsy Needle Assembly) - Ejector Pin - Ejector guide • Pouch set: - Power Driver Pouch - Coupler
	Bone Lesion	OnControl™ Bone Lesion Biopsy Tray - Transfer Rod - Bone Access Ejector Rod - Bone Access Needle Set - Bone Lesion Biopsy Needle - Bone Lesion Biopsy Ejector Rod - Depth Stop - Manual Handle - Connector Hub with Sterile Sleeve - Fenestrated Drape - Ejector Assistant	OmniBone™ Bone Biopsy Kit with Power Driver Pouch • Needle set: - Bone Access Introducer (Outer cutting Cannula + Drill tip Stylet + depth gauge assembly) - Trephine Biopsy Needle (Trephine Outer Cannula + Stiffener + depth gauge assembly) - Ejector Pin - Handle - Holder • Pouch set: - Power Driver Pouch - Coupler
Gauge Sizes	Bone Marrow	Biopsy Cannula:11G	Biopsy Cannula: 11G
	Bone Lesion	Access Cannula: 10G and 11G Biopsy Cannula: 12G and 13G	Introducer Cannula: 11G Trephine Outer Cannula: 13G

Characteristic		Predicate **OnControl™ Powered Bone Access System** OnControl™ Bone Marrow Biopsy System - K142377 OnControl™ Bone Access and Bone Biopsy System - K113872	Subject **OmniBone™ Powered Biopsy System** OmniBone™ Bone Marrow Biopsy Kit with Power Driver OmniBone™ Bone Biopsy Kit with Power Driver
Overall Needle Assembly Length	Bone Marrow	Biopsy Needle Assembly: 102 and 152 mm	Biopsy Needle Assembly: 100 and 150 mm
	Bone Lesion	Bone Access Needle Assembly: 62, 102 and 152 mm	Bone Access Introducer Assembly: 65,5, 106 and 156 mm
		Biopsy Needle Assembly: 108, 148, and 198 mm	Biopsy Trephine Assembly: 154,194,5 and 234,5mm
Biopsy Kits - Sterility		Single Use, Ethylene Oxide	Single Use, Ethylene Oxide
Power Driver - Sterility		Reusable, non-sterile. Used with Single Use Disposable Sterile Sleeve with Connector Hub	Reusable, non-sterile. Used with Single Use Disposable Sterile Pouch and Coupler
Power Driver - Disinfection		Disinfected utilizing an antimicrobial solution	Disinfected utilizing an antimicrobial solution

The predicate device is the OnControl™ Powered Bone Access System, which is comprised of the *OnControl™ Bone Marrow Biopsy System* and the *OnControl™ Bone Access and Bone Biopsy System*. The OnControl™ Powered Bone Access System is referenced as the predicate device for the OmniBone™ Powered Biopsy System as it is **the same or similar to the subject device** in the following ways:

a. **Intended Use**
b. **Indications for Use**

- The OmniBone™ Bone Biopsy Kit with Power Driver shares the same indications for use as the predicate OnControl™ Bone Access and Bone Biopsy System as they share a subset of the OnControl™ Bone Access and Bone Biopsy System. The subject device and the predicate device are both indicated for the sampling of bone biopsies from the vertebral body and from bone lesions. Indications for vertebroplasty have been omitted.
- The OmniBone™ Bone Marrow Biopsy Kit with Power Driver shares the same indications for use as the predicate OnControl Bone Marrow Biopsy System as they are both indicated for bone marrow aspiration and biopsy in adult patients. Indication for pediatric patients has been omitted.

c. **Target population**
d. **Fundamental Scientific Technology**
e. **Performance characteristics**

f. Operating Principle, Mechanism of action

g. Sterility Assurance Level and method of Sterilization

The subject device is **different from the predicate device** in the following ways:

- **Enhanced Power Driver Technology**
  a. Variable Speed Functionality: The subject device utilizes a variable speed Power Driver. The variable speed functionality was designed to allow the user to control the speed of the needle rotation depending on their needs and the type of procedure being performed.
  b. The subject device's offers 2 possible driving motion: reverse and forward and is controlled by a 3-position switch. The addition of a reverse motion eases the introduction of the access needle through soft tissue and the removal of the needles from the bone.
  c. Reference LED Indicator that displays Power Level: The subject device utilizes a Reference LED indicator that displays 3 level of Power Level.
  d. Rechargeable: the subject device has a DC jack connector and is rechargeable via a dedicated Charger.
  e. Driveshaft: the subject device has no driveshaft extending from the housing but a fully integrated female connector instead facilitating the cleaning of the Power Driver. This difference has no impact on mode of action or on safety.

- **Biopsy Kit Components**
  a. Optimized Biopsy and Introducer Cannula Dimensions and Tip Design: The subject device Biopsy and Introducer Cannulas feature enhanced designs for optimal sample acquisitions.
  b. Unlike the connector sleeve of the Predicate, the subject device has a sterile pouch and a sterile coupler that are not factory-assembled together. The pouch and the coupler are assembled during the procedure. This design has no impact on the efficiency of the barrier-like system and shows the same level of performance and safety than the predicate.
  c. Handle Manual Driver (Bone Biopsy Kit): The subject device's Manual Driver has a Handle and attaches to the needle assembly via an interfacing and locking mechanism.
  d. Easy Connect Release Mechanism: The subject device is designed to release the Needle Assembly from the Power Driver by simply pressing the releasable locking fins of the Luer-Hub of the needles.

7. Performance Data

The OmniBone™ Powered Bone Biopsy System which includes the OmniBone™ Power Driver, the OmniBone™ Charger, the OmniBone™ Bone Biopsy Kit with Power Driver Pouch and the OmniBone™ Bone Marrow Biopsy Kit with Power Driver Pouch was tested to evaluate its performances and support the determination of substantial equivalence.

The following tests were performed on the subject device:

- Battery charging time
- Battery capacity
- Tissue sampling
- Reliability Testing – Power Driver Pouch Sealing
- Rotation Speed
- Needle Penetration Force
- Power Driver – Coupler Reliability
- Tensile Strength – Needle hub
- Creep Testing
- Dead Space Measurements

Additionally, biocompatibility testing was performed in accordance with ISO 10993-1 to demonstrate that the OmniBone™ Powered Biopsy System is biocompatible for its intended use. Sterilization was performed in accordance with ISO 11135:2014 to confirm the Sterility Assurance Level (SAL) of 10-6 for the OmniBone™ Biopsy Kits. The label shelf life is 5 years. Electromagnetic Compatibility and Electrical Safety Testing were performed on the OmniBone™ Power Driver and Charger in accordance with IEC 60601-1 and 60601-2. The results from this testing demonstrate that the OmniBone™ Power Driver and Charger meets electrical safety and performance requirements established, and acceptance criteria for all tests were met. The subject device OmniBone™ Powered Biopsy system (OmniBone™ Power Driver, OmniBone™ Charger, OmniBone™ Bone Biopsy Kit with Power Driver Pouch, OmniBone™ Bone Marrow Biopsy Kit with Power Driver Pouch) met all the predetermined acceptance of design verification and validation as specified by applicable standards, guidance, tests protocols and/or customer inputs.

8. Conclusion

The proposed **OmniBone™ Powered Biopsy System** (OmniBone™ Power Driver, OmniBone™ Charger, OmniBone™ Bone Biopsy Kit with Power Driver Pouch, OmniBone™ Bone Marrow Biopsy Kit with Power Driver Pouch) and the predicate share the same or similar intended use, indications for use, target population, technological characteristics and fundamental scientific technology. Therefore, Laurane Medical SAS has demonstrated that the subject device OmniBone™ Powered Biopsy System (OmniBone™ Power Driver, OmniBone™ Charger, OmniBone™ Bone Biopsy Kit with Power Driver Pouch, OmniBone™ Bone Marrow Biopsy Kit with Power Driver Pouch) is substantially equivalent to the legally marketed predicate device OnControl™ Bone Marrow Biopsy System and OnControl™ Bone Access and Bone Biopsy System, respectively.