January 18, 2023

MOLLI Surgical, Inc
% Pierre Bounaud
Principal consultant
Rqm+
2251 San Diego Ave, B-257
San Diego, California 92110

Re: K223107
Trade/Device Name: MOLLI 2
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: December 7, 2022
Received: December 20, 2022

Dear Pierre Bounaud:

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,

Deborah A. Fellhauer -S

Deborah Fellhauer, RN, BSN
Assistant Director
Plastic Surgery Implant Dvices Team
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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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)*
K223107

Device Name
MOLLI 2

Indications for Use *(Describe)*
The MOLLI Marker is intended to be placed percutaneously in soft tissue to temporarily mark a surgical site intended for surgical removal. The MOLLI Marker can only be implanted for less than 30 days. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (MOLLI 2 System), the MOLLI Marker is located and surgically removed with the target tissue.

The MOLLI 2 System is intended only for the non-imaging detection and localization of the MOLLI Marker that has been implanted in a site intended for surgical removal.

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

DATE PREPARED
September 30, 2022

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DEVICE INFORMATION
Proprietary Name/Trade Name: MOLLI 2

Common Name:	Implantable radiographic marker
Regulation Number:	21 CFR 878.4300
Class:	II
Product Code:	NEU
Premarket Review:	OPEQ/OHT4/Infection Control and Plastic Surgery Devices (DHT4B)
Review Panel:	General & Plastic Surgery

PREDICATE DEVICE IDENTIFICATION
MOLLI 2 is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K210600	MOLLI / MOLLI Surgical, Inc.	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
MOLLI 2 is a precision surgical marking and guidance system for locating non-palpable lesions during surgery. MOLLI 2 consists of a temporary marker (MOLLI Marker), a marker delivery system (MOLLI Introducer), a detection wand (MOLLI Wand 2), and a visualization tablet (MOLLI Tablet 2). The MOLLI Wand 2 and MOLLI Tablet 2 constitute the MOLLI 2 System. The MOLLI 2 System is intended for the non-imaging detection and localization of the MOLLI Marker that has been implanted in a site intended for surgical removal.

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The purpose of this 510(k) premarket notification is to introduce the following changes to the previously cleared MOLLI device:

- Addition of a new needle length for the MOLLI Introducer
- Hardware and software updates to the guidance system components (MOLLI Wand 2, MOLLI Tablet 2)

INDICATIONS FOR USE

The MOLLI Marker is intended to be placed percutaneously in soft tissue to temporarily mark a surgical site intended for surgical removal. The MOLLI Marker can only be implanted for less than 30 days. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (MOLLI 2 System), the MOLLI Marker is located and surgically removed with the target tissue.
The MOLLI 2 System is intended only for the non-imaging detection and localization of the MOLLI Marker that has been implanted in a site intended for surgical removal.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

MOLLI Surgical, Inc. believes that MOLLI 2 is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use, design, and technological characteristics as the predicate device cleared in K210600. Minor modifications to the subject device as compared to the predicate device include:

- MOLLI Introducer: addition of a longer needle (12 cm)
- MOLLI Wand 2: new circuit board, minor changes to internal components, cosmetic changes, firmware update
- MOLLI Tablet 2: component update (new screen, battery and speakers) and software update

These changes have undergone testing to ensure the device is as safe and effective as the predicate device.

SUMMARY OF NON-CLINICAL TESTING

The materials/formulation and processing of the patient-contacting components of the MOLLI 2 are the same as for the predicate device. Therefore, MOLLI 2 is considered to have met the requirements of ISO 10993-1 and FDA's *Guidance for Industry and Food and Drug Administration Staff – Use of International ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.

The following tests were performed to demonstrate safety based on current industry standards:

- EO sterilization validation per ISO 14937 and ISO 10993-7
- Software testing per IEC 62304
- Electrical safety testing per IEC 60601-1 and IEC 60601-1-6
- EMC testing per IEC 60601-1-2
- Non-clinical performance bench testing

The results of these tests indicate that MOLLI 2 is substantially equivalent to the predicate device.

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CONCLUSION

Based on the testing performed, including sterilization validation testing, software testing, electrical safety testing, EMC testing, and non-clinical performance bench testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The same indications for use, technological characteristics, and performance characteristics for the proposed MOLLI 2 are assessed to be substantially equivalent to the predicate device.