September 25, 2024

MOLLI Surgical, Inc.
John Dillon,
Chief Technology Officer
50 Wellington Street East
Suite 400
Toronto, ON M5E 1C8
Canada

Re: K240042
Trade/Device Name: MOLLI 2 System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: August 22, 2024
Received: August 26, 2024

Dear John Dillon,:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.09.25 12:55:49 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240042

Device Name
MOLLI 2 System

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 be implanted for greater than 30 days. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (MOLLI Systems (MOLLI System and MOLLI 2 System)), the MOLLI Marker is located and surgically removed with the target tissue.

The MOLLI Systems (MOLLI System and MOLLI 2 System) are 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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PRAStaff@fda.hhs.gov

"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

DATE PREPARED

August 26, 2024

MANUFACTURER AND 510(k) OWNER

MOLLI Surgical, Inc.
50 Wellington Street East Suite 400 Toronto ON M5E 1C8 Canada
Telephone: +1-416-805-7582
Official Contact: John Dillon, Chief Technology Officer
Email: jdillon@mollisurgical.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	MOLLI 2 System
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*
K231579	MOLLI 2 / MOLLI Surgical, Inc.	✓

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

DEVICE DESCRIPTION

The MOLLI Systems (MOLLI System and MOLLI 2 System) are precision surgical marking and guidance systems for locating non-palpable lesions during surgery. The systems consist of a temporary marker (MOLLI Marker), a marker delivery system (MOLLI Introducer), a detection wand (MOLLI Wand/MOLLI 2 Wands), and a visualization tablet (MOLLI Tablet/MOLLI Tablet 2). The MOLLI Wand/MOLLI 2 Wand Family and MOLLI Tablet/MOLLI 2 Tablet constitute the system. The MOLLI 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.

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

- Update of Indications of Use statement to indicate that the MOLLI Marker may be implanted for greater than 30 days.

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 be implanted for greater than 30 days. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (MOLLI Systems (MOLLI System and MOLLI 2 System)), the MOLLI Marker is located and surgically removed with the target tissue.

The MOLLI Systems (MOLLI System and MOLLI 2 System) are 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 the subject device is substantially equivalent to the predicate device. The subject device has the same design, and technological characteristics as the predicate devices cleared in K231579. Minor modifications to the subject device as compared to the predicate device include:

- Update of Indications of Use statement to indicate that the MOLLI Marker may be implanted for greater than 30 days.

SUMMARY OF NON-CLINICAL TESTING

Due to the change in MOLLI Marker implant duration, additional non-clinical testing was performed.

The following reports are included in this submission to demonstrate safety and effectiveness based on current industry standards:

- Biocompatibility testing to demonstrate the safety of the MOLLI Marker

The results of these reports indicate that the subject device is substantially equivalent to the predicate device.

CONCLUSION

Based on the testing performed, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device.