April 16, 2021

MOLLI Surgical, Inc.
% Pierre Bounaud
Principal Consultant
AcKnowlegde Regulatory Strategies, LLC
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

Re: K210600
Trade/Device Name: Molli
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: February 26, 2021
Received: March 1, 2021

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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K210600

Device Name
MOLLI

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 System), the MOLLI Marker is located and surgically removed with the target tissue.

The MOLLI 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.

***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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*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**
February 26, 2021

**MANUFACTURER AND 510(k) OWNER**
MOLLI Surgical, Inc.
22 St. Clair Ave. East, Suite #1500, Toronto, ON M4T 2S3, Canada
Telephone: +1 (833) 665-5463
Official Contact: Fazila Seker, President & CEO

**REPRESENTATIVE/CONSULTANT**
Pierre Bounaud, Ph.D.
Allison C. Komiyama, Ph.D., R.A.C.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 458-9547
Email: pbounaud@acknowledge-rs.com, akomiyama@acknowledge-rs.com
Website: www.AcKnowledge-RS.com

**DEVICE INFORMATION**

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

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

| *510(k) Number* | *Predicate Device Name / Manufacturer* | *Primary Predicate* |
|---|---|---|
| K181007 | Cianna Medical SAVI Scout Reflector and SAVI Scout System / Cianna Medical, Inc. | ✓ |
| K163541 | Magseed Magnetic Marker System / Endomagnetics, Ltd | |

The predicate devices have not been subject to a design related recall.

510(k) Summary

molli

**DEVICE DESCRIPTION**

MOLLI is a precision surgical marking and guidance system for locating non-palpable lesions during surgery. MOLLI consists of a temporary marker (MOLLI Marker), a marker delivery system (MOLLI Introducer), a detection wand (MOLLI Wand), and a visualization tablet (MOLLI Tablet). The MOLLI Marker is preloaded in the MOLLI Introducer. The MOLLI Wand and the MOLLI Tablet constitute the MOLLI 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.

**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 System), the MOLLI Marker is located and surgically removed with the target tissue.

The MOLLI 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 believes that MOLLI is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions, and uses similar or identical materials as the devices cleared in K181007 and K163541. The subject device has the same intended use, similar technological characteristics, and similar instrumentation to the devices cleared in K181007 and K163541.

Technological differences of the subject device compared to the device cleared in K181007 include:

- Energy type used in the localization of the implantable marker.
- Reusable handheld probe.
- User calibration of the detection system.

These technological differences have undergone testing to ensure the device is substantially equivalent to the predicate.

**SUMMARY OF NON-CLINICAL TESTING**

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

- Biocompatibility testing per ISO 10993-1
- Packaging validation testing per ISO 11607-1 and ASTM D4169-19

- EO sterilization validation per ISO 14937 and ISO 10993-7
- Software testing per IEC 62304
- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2:2014
- MRI compatibility testing per ASTM standards F2052-15, F2119-07, F2182-11, and F2213-17.
- Non-clinical performance bench testing including V&V testing, MOLLI Marker displacement testing, tissue performance testing, and needle penetration testing (per ISO 7864)
- Human factor validation testing

**CONCLUSION**

MOLLI is considered substantially equivalent to the predicate devices based on the testing performed, the identical indications for use, and similar technological characteristics. Based on the testing performed, including biocompatibility testing, packaging validation testing, sterilization validation testing, software testing, electrical safety testing, EMC testing, MRI compatibility testing, non-clinical performance bench testing, and human factor validation testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device.