



September 27, 2024

OptMed, Inc.
% Allison Komiyama
VP, MedTech Innovations
Rqm+
2790 Mosside Blvd.
Suite 800
Monroeville, Pennsylvania 15146

Re: K241916
Trade/Device Name: TearRepair Liquid Skin Protectant
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid Bandage
Regulatory Class: Class I, reserved
Product Code: KMF
Dated: June 28, 2024
Received: July 1, 2024

Dear Allison Komiyama:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.

Assistant Director

DHT4B: Division of 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

Indications for Use

510(k) Number (if known)
K241916

Device Name
TearRepair Liquid Skin Protectant

Indications for Use (Describe)

TearRepair is intended to be used in areas exposed to mechanical forces such as friction and shear from bedding, clothing, shoes, or any material that may damage the skin. TearRepair can also be used to protect skin exposed to irritation from moisture such as urine, feces, digestive juices, perspiration, and wound drainage. TearRepair can also help protect the skin against irritation caused by adhesive products.

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
PRASStaff@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

September 23, 2024

MANUFACTURER AND 510(k) OWNER

OptMed, Inc.

745 Fifth Ave., Suite 500

New York, New York 10151

Telephone: +1 908-720-2372

Official Contact: Nitasha Yajnik, Associate Director, Quality and Regulatory Assurance

REPRESENTATIVE/CONSULTANT

Allison C. Komiyama, Ph.D., RAC (RQM+)

Lucie Dalet, Ph.D. (RQM+)

Bhoomika Joyappa (Medical Device Academy, Inc.)

Telephone: +1 (412) 816-8139

Email: akomiyama@rqmplus.com

ldalet@rqmplus.com

DEVICE INFORMATION

Proprietary Name/Trade Name: TearRepair Liquid Skin Protectant

Common Name: Bandage, Liquid

Regulation Number: 21 CFR 880.5090

Class: I

Product Code: KMF

Premarket Review: Office of Surgical and Infection Control Devices (OHT4)
Infection Control and Plastic and Reconstructive Surgery
Devices (DHT4B)

Review Panel: General & Plastic Surgery

PREDICATE DEVICE IDENTIFICATION

TearRepair is substantially equivalent to the following predicate:

<i>510(k) Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>
K133443	Marathon No Sting Liquid Skin Protectant/ Advanced Medical Solutions (Plymouth) Ltd.	✓

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

DEVICE DESCRIPTION

TearRepair Liquid Skin Protectant is a rapid-drying liquid barrier film for the protection of the skin. It is applied as a liquid and dries within minutes, adhering to the contours of the skin to form a transparent flexible film. TearRepair will wear off, naturally, and is provided as a single-use, sterile device provided as Rx Only.



INDICATIONS FOR USE

TearRepair is intended to be used in areas exposed to mechanical forces such as friction and shear from bedding, clothing, shoes, or any material that may damage the skin. TearRepair can also be used to protect skin exposed to irritation from moisture such as urine, feces, digestive juices, perspiration, and wound drainage. TearRepair can also help protect the skin against irritation caused by adhesive products.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

OptMed, Inc. believes that the TearRepair is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and uses similar materials as the device cleared in K133443. The subject device has the similar intended use and similar technological characteristics to the devices cleared in K133443. The device has similar instrumentation to the device cleared in K133443. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicates.

	Subject Device <i>TearRepair Liquid Skin Protectant</i>	Primary Predicate Device <i>Marathon No Sting Liquid Skin Protectant</i>	Comparison
Manufacturer	OptMed, Inc.	Advanced Medical Solutions	N/A
510(k) Number	TBD	K133443	N/A
Device Image			N/A
Single-Use	Yes	Yes	Equivalent
Patient Population	Adults over the age of 21	Unknown	Equivalent

	Subject Device <i>TearRepair Liquid Skin Protectant</i>	Primary Predicate Device <i>Marathon No Sting Liquid Skin Protectant</i>	Comparison
Indications for Use	TearRepair is intended to be used in areas exposed to mechanical forces such as friction and shear from bedding, clothing, shoes, or any material that may damage the skin. TearRepair can also be used to protect skin exposed to irritation from moisture such as urine, feces, digestive juices, perspiration, and wound drainage. TearRepair can also help protect the skin against irritation caused by adhesive products.	Marathon No Sting Liquid Skin Protectant helps protect skin exposed to Irritation from moisture such as urine, feces, digestive juices, perspiration, and wound drainage. Marathon No Sting Liquid Skin Protectant can also be used in areas that are exposed to friction and shear from bedding, clothing, shoes, or any material that will rub against the skin. Marathon No Sting Liquid Skin Protectant helps protect the skin against Irritation caused by adhesive products.	Equivalent
Type of Use	Prescription (Rx Only)	Prescription (Rx Only)	Equivalent
Operating Principle	The healthcare provider actuates the device by squeezing the applicator walls, crushing the glass ampoule within allowing the adhesive to flow to the application tip. The adhesive is applied as a liquid and polymerizes, adhering to the contours of the skin to form a transparent, flexible film. TearRepair wears off naturally as the skin regenerates.	The adhesive is accessed by crushing the glass ampoule. This is achieved by holding it vertically with the tip upper most, and then the glass ampoule is broken by squeezing the applicator walls between finger and thumb. The adhesive is expressed by inverting the applicator and gently squeezing the applicator body until the adhesive wets the tip of the applicator. The adhesive	Equivalent

	Subject Device <i>TearRepair Liquid Skin Protectant</i>	Primary Predicate Device <i>Marathon No Sting Liquid Skin Protectant</i>	Comparison
		is applied to the required area as a thin film and allowed to polymerize solid.	
Monomer	Methylidene malonate	Cyanoacrylate	Similar; both are monomer/polymer materials; does not raise issues of safety and effectiveness based on performance, biocompatibility, sterilization and shelf-life testing.
Dispenser	Applicator sleeve containing a glass ampoule that, when crushed, allows for expressing the adhesive through the tip; Polyolefin/PP Molded tip	Applicator sleeve containing a glass ampoule that, when crushed, allows for expressing the adhesive through the tip; Sponge applicator	Similar; applicator tip of subject device is made of a polyolefin/PP molded part while the predicate device has a sponge applicator. Performance testing does not raise new issues of safety and effectiveness.
Outer Plastic Tube	Yes	Yes	Equivalent
Applicator Tip Shape	Domed	Deerfoot	Similar; applicator functionality testing performed to support equivalent

	Subject Device <i>TearRepair Liquid Skin Protectant</i>	Primary Predicate Device <i>Marathon No Sting Liquid Skin Protectant</i>	Comparison
			performance to the predicate.
Adhesive	Yes	Yes	Equivalent
Stability and Shelf-life	<ul style="list-style-type: none"> • Real Time Aged Product • Environmental Conditioning and Distribution Testing • Product Stability Testing • Package integrity 	Unknown; Redacted from 510(k).	Similar; testing demonstrates that the device is substantially equivalent to predicate
Sterilization	Gamma Irradiation	EtO	Similar; both products sterilized according to validated processes

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for TearRepair. The following tests were performed to demonstrate safety based on current industry standards:

Bench Testing:

- Mechanical Testing/Adhesive strength testing
- Heat of Polymerization
- Moisture Vapor Transmission Rate
- Setting Time of Liquid Skin Protectant
- Applicator Functionality

Biocompatibility:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)
- Acute systemic toxicity (ISO 10993-11)
- Material-mediated pyrogenicity (ISO 10993-11, USP <151>)
- Subacute toxicity (ISO 10993-11)
- Implantation (ISO 10993-6)

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

CONCLUSION

Based on the testing performed, including wound closure strength, shear strength, and tensile strength, and biocompatibility testing, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed TearRepair are assessed to be substantially equivalent to the predicate device.