



9/19/2025

OptMed, Inc.
% Lucie Dalet
Principal Consultant
Rqm+
2790 Mosside Blvd.
Suite 800
Monroeville, Pennsylvania 15146

Re: K243990

Trade/Device Name: BondEase 2 Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: August 25, 2025
Received: August 25, 2025

Dear Lucie Dalet:

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,

Wilmarie Flores -S  Digitally signed by
Wilmarie Flores -S

For Jodie Giordano, Ph.D.
Acting 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)
K243990

Device Name
BondEase 2 Topical Skin Adhesive

Indications for Use (Describe)

BondEase® 2 Topical Skin Adhesive is intended for topical use only, to hold together the skin edges of incisions and lacerations that are under minimal tension and easily approximated. Where significant tension exists on incisions or lacerations, BondEase® 2 Topical Skin Adhesive should be used in conjunction with deep dermal stitches.

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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510(k) SUMMARY

DATE PREPARED

September 18, 2025

MANUFACTURER AND 510(k) OWNER

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DEVICE INFORMATION

Proprietary Name/Trade Name: BondEase 2 Topical Skin Adhesive
 510(k) Number: K243990
 Common Name: Tissue Adhesive For The Topical Approximation Of Skin
 Regulation Number: 21 CFR 878.4010
 Class: II
 Product Code: MPN
 Premarket Review: Division of Health Technology 4 B (Plastic and Reconstructive Surgery Devices)
 Review Panel: General & Plastic Surgery

PREDICATE DEVICE IDENTIFICATION

BondEase 2 is substantially equivalent to the following predicates:

<i>510(k) Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>
K152096	Dermabond Advanced Topical Skin Adhesive / Ethicon, Inc.	✓
K141157	BondEase Topical Skin Adhesive / OptMed, Inc.	

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

DEVICE DESCRIPTION

BondEase 2 Topical Skin Adhesive is a sterile, liquid topical skin closure device composed of a methylidene malonate monomer formulation. The adhesive is composed of two solutions which must be mixed to polymerize: the methylidene malonate monomer solution (Part A) and the polymerization activator solution (Part B). BondEase 2 is provided as a single-use applicator, packaged in a foil pouch. The applicator comprises a plastic tube containing a crushable glass

ampoule, a porous filter, and a tip subassembly, which is inserted into a plastic handle. With the exception of the plastic handle, the device is identical in design, formulation, and manufacturing, to the reference device TearRepair Liquid Skin Protectant cleared in K241916.

INDICATIONS FOR USE

BondEase® 2 Topical Skin Adhesive is intended for topical use only, to hold together the skin edges of incisions and lacerations that are under minimal tension and easily approximated. Where significant tension exists on incisions or lacerations, BondEase® 2 Topical Skin Adhesive should be used in conjunction with deep dermal stitches.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

OptMed, Inc. believes that BondEase 2 is substantially equivalent to the predicate devices based on the information summarized here:

Both the subject and predicate devices are intended for the topical approximation of skin edges of incisions and lacerations. While the subject device and the primary predicate device cleared in K152096 have different formulations and dispenser designs, the principle of operation, mechanism of action, and conditions of use are identical. The subject device has a similar design and uses the same monomer as the predicate device cleared in K141157 for the same intended use. Since the differences in formulation and dispenser design do not impact the indications for use, principle of operation, or conditions of use of the device, they do not raise different questions of safety and effectiveness compared to the primary predicate device. These technological characteristics have undergone testing to ensure the device is substantially equivalent to the primary predicate.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate substantial equivalence based on current industry standards as recommended by FDA in the Special Controls Guidance *Tissue Adhesive for the Topical Approximation of Skin*:

Biocompatibility:

Biocompatibility testing performed on the subject device included:

- 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 / implantation (ISO 10993-11 and ISO 10993-6)

Bench Testing:

- Mechanical Testing:
 - Wound Closure Strength per ASTM F2458-05 *Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants*

- Tensile Strength per ASTM F2258-05 *Standard Test Method for Strength Properties of Tissue Adhesives in Tension*
- Shear Strength per ASTM F2255-05 *Standard Test Method for Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading*
- Hydrolytic Degradation
- Heat of Polymerization
- Microbial Barrier
- Applicator Functionality
- Design Specifications Testing

Animal Testing:

A porcine study was conducted to evaluate the healing process and local skin reactions to the subject device. The subject device and predicate device were used to treat full-thickness linear incisions in a porcine model and the healing and biological response of the treatment sites were determined.

CONCLUSION

Based on the testing performed, including adhesive strength testing, hydrolytic degradation, heat of polymerization, microbial barrier, applicator functionality, and design specification testing, as well as animal 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 BondEase 2 Topical Skin Adhesive are assessed to be substantially equivalent to the predicate devices.