DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 22, 2015

OptMed, Inc.
Stephanie Rais
Regulatory Consultant
601 Lexington Avenue, Suite 5100
New York, New York 10022

Re: K141157
Trade/Device Name: BondEase Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: December 7, 2015
Received: December 8, 2015

Dear Ms. Rais:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141157

Device Name
BondEase® Topical Skin Adhesive

Indications for Use *(Describe)*

BondEase® 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® Topical Skin Adhesive should be used in conjunction with deep dermal stiches.

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

510(k) Owner	OptMed, Inc. 601 Lexington Avenue, Suite 5100 New York, New York 10022 Telephone: 212-867-4141 Fax: 917-720-9961
Contact Person	Alain Klapholz
Date	December 21, 2015
Trade Name	BondEase®
Common Name	Topical Skin Adhesive
Classification Name	Tissue Adhesive for Topical Approximation of Skin
Review Panel	General & Plastic Surgery
Product Code	MPN
Regulation	Class II, 21 C.F.R. § 878.4010
Predicate Devices:	DERMABOND® Topical Skin Adhesive (P960052) INDERMIL® Tissue Adhesive (P010002)

Device Description

BondEase® Topical Skin Adhesive is a sterile, liquid topical skin closure device composed of a methylidene malonate monomer formulation and the colorant D&C Green #6. It is provided in a single-use applicator, packaged in a foil pouch. The applicator is comprised of a crushable glass ampoule contained within a plastic vial with attached applicator tip and handle.

BondEase® is applied to the skin as a viscous liquid which polymerizes to bond approximated wound edges within minutes. In vitro studies have shown that BondEase® acts as a bacterial barrier as long as the adhesive film remains intact.

Indications for Use

BondEase® 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® Topical Skin Adhesive should be used in conjunction with deep dermal stiches.

Technological Characteristics Compared to Predicates

The technological characteristics of BondEase® Topical Skin Adhesive are similar to those of the predicate devices in that they use similar polymerization mechanisms and have similar monomer structures. The predicate devices are cyanoacrylate formulations while BondEase® is formulated from methylidene malonate. For all products, the adhesives polymerize after being applied to the skin. BondEase® and the predicate devices are supplied in a dispensing applicator and are applied to the wound in a continuous film binding the approximated wound edges together. BondEase® and the predicate devices are supplied sterile and are for single use. As with the other topical skin adhesives, BondEase® is designed to bond approximated wound edges to provide flexible wound closure and provide a bacterial barrier as long as the adhesive remains intact. BondEase® and the predicate devices have substantially equivalent indications for use and mechanism of action.

Nonclinical Performance Data

BondEase® Topical Skin Adhesive was evaluated in accordance with FDA's Guidance for Industry: Class II Special Controls Guidance Document: Tissue Adhesive for Topical Approximation of Skin.

Performance Bench Testing included various tests of adhesive strength and tests for degradation rate, heat of polymerization, and bacterial barrier performance. In these studies, BondEase® met all performance requirements.

Biocompatibility Testing was conducted per ISO 10993 guidelines and test results showed BondEase® to be non-cytotoxic, non-irritating, non-pyrogenic, with no toxicological affect 30 days post implantation. BondEase® was also found to be non-hemolytic and non-genotoxic. The full list of biocompatibility tests follows.

Cytotoxicity
Sensitization
Irritation
Systemic Toxicity – Acute Systemic & Material Mediated Pyrogen
Implantation and Subchronic Toxicity
Genotoxicity – Ames, Mouse Lymphoma & Mouse Micronucleus
Hemolysis – Extract & Direct Contact
Endotoxicity

In a porcine study conducted, results demonstrated that BondEase® did not inhibit normal wound closure and healing, and support that BondEase® may be used for the approximation of skin without the use of subcutaneous sutures on small, tensionless incisions. BondEase® Topical Skin Adhesive has demonstrated substantial equivalence to DERMABOND®, which was used as a control.

Clinical Performance Data

A prospective, randomized, controlled, open-label study was conducted to evaluate the ability of BondEase® Topical Skin Adhesive to close approximated skin edges of traumatic lacerations and surgical incisions in comparison to Conventional Wound Closure Devices (CWCD) including sutures, staples, or adhesive strips, with or without sutures placed below the skin surface according to investigator judgment. The study was designed to demonstrate that BondEase is non-inferior to conventional wound closure devices (CWCD) in terms of 100% wound edge apposition of surgical incisions and traumatic lacerations.

The study population included patients at least one year of age, in good general health. Patients were excluded if presenting with: significant multiple trauma, peripheral vascular disease, insulin dependent diabetes mellitus, blood clotting disorder, keloid formation or hypertrophy history (patient or family), allergy to the adhesive, burst or stellate lacerations, animal or human bite, HIV, decubitus ulcer, heavily contaminated wounds and evidence of active infection or gangrene. Wound length and width were measured in millimeters; wound depth was not measured according to the study protocol. Types of wounds included traumatic lacerations and surgical incisions with and without deep dermal sutures. The study sample size was calculated based on the assumption of 95% wound apposition rate with BondEase compared to 96% wound apposition rate with CWCD. Based on this assumption, a total of 144 subjects would provide 80% statistical power to demonstrate equivalence with a clinically acceptable 10% margin and a one-sided Type I error rate of 0.05. Table 1 summarizes the subject accountability and Table 2 summarizes the demographic characteristics and baseline wound types. The following

factors had no impact on the performance of BondEase® Topical Skin Adhesive in terms of 100% wound edge apposition at day 10: wound type, gender, age, or race, the need for deep dermal sutures, and the location of the wound.

Table 1: Subject Accountability

	BondEase	CWCD	Total
Randomized*	108	54	162
Randomized and treatment applied	105 (97.2%)	54 (100%)	159 (98.1%)
Completed the study	100 (92.6%)	51 (94.4%)	151 (93.2%)
Early discontinuation**	8 (7.4%)	3 (5.6%)	11 (6.8%)
Intent-to-treat population (ITT)	105 (97.2%)	54 (100%)	159 (98.1%)
Per protocol population (PP)	100 (92.6%)	53 (98.1%)	153 (94.4%)

*20 BondEase and 10 CWCD subjects were enrolled in Part 1 of the clinical study. 88 BondEase and 44 CWCD subjects were enrolled in Part 2 of the clinical study.

**Reasons for early discontinuation included subjects that (1) were randomized but not treated, (2) voluntarily withdrew, (3) were non-compliant, (4) lost to follow-up, (5) had some other medical reason.

Table 2: Demographic Characteristics and Baseline Wound Types by Treatment Group (ITT Population)

	BondEase N=105	CWCD N=54	Total N=159
Age (years)			
Mean (SD)	44.4 (23.1)	47.7 (22.3)	45.5 (22.8)
Median	46	47	46
Min-Max	1 – 93	3 – 87	1 – 93
Gender			
Male, n (%)	56 (53.3%)	30 (55.6%)	86 (54.1%)
Female, n (%)	49 (46.7%)	24 (44.4%)	73 (45.9%)
Race			
White or Caucasian, n (%)	83 (79.0%)	46 (85.2%)	129 (81.1%)
Black or African American, n (%)	16 (15.2%)	7 (13.0%)	23 (14.5%)
Asian, n (%)	2 (1.9%)	1 (1.9%)	3 (1.9%)
Other, n (%)	4 (3.8%)	0 (0.0%)	4 (2.5%)
Ethnicity			
Not Hispanic / Latino, n (%)	84 (80.0%)	49 (90.7%)	133 (83.6%)
Hispanic or Latino, n (%)	21 (20.0%)	5 (9.3%)	26 (16.4%)
Wound type			
Injury (Laceration)	27 (25.7%)	13 (24.1%)	40 (25.2%)
Surgical incision	78 (74.3%)	41 (75.9%)	119 (74.8%)

Adverse events with BondEase were of the same type as seen with other tissue adhesives. In the clinical study, both treatments appeared to be well-tolerated. There were no deaths, no treatment-related serious adverse events, device-related complications or infections. There were no events of wound dehiscence requiring supplemental closure. All device-related adverse events were mild and appeared to have no impact on the cosmesis outcome. Signs of inflammation at the wound site were comparable between treatment groups. Table 3 summarizes these results.

Table 3: Device-related adverse reactions encountered during the clinical study (ITT Population)

Clinical Study Outcomes	**BondEase®**	**Control (CWCD)**
	N (%)	**N (%)**
Dehiscence with No Need for Retreatment	2 (1.9%)	0 (0%)
Mild Scar	2 (1.9%)	0 (0%)
Acute Inflammation at 10 days		
Erythema	7 (6.7%)	4 (7.4%)
Edema	1 (1.0%)	0 (0.0%)
Pain	2 (1.9%)	2 (3.7%)
Total AEs	14	6

Efficacy assessments included percent wound apposition as determined by the investigator and cosmetic outcome of the wound using a validated scale [Hollander JE, et al, 1995] as determined by a blinded clinician. The effectiveness outcomes measured were: (1) the proportion of subjects in whom 100% wound edge apposition was achieved at 10 days (± 3 days) post-procedure; (2) the incidence of $\geq$50% wound apposition at 10 days (± 3 days) post-procedure; (3) the incidence of wounds with an optimal cosmetic outcome (score of 6) at 28 days (± 5 days) and (4) the mean and median cosmesis scores at 28 days (± 5 days). The efficacy results are presented in Tables 4, 5 and 6.

Table 4: 100% Wound Apposition at 10 Days by Treatment Group

	BondEase	CWCD	BondEase-CWCD	95% CI**
Per protocol population*	77.1% (74/96)	80.4% (41/51)	-0.03	-0.13 to 0.11
Intent-to-treat population	73.3% (77/105)	77.8% (42/54)	-0.04	-0.13 to 0.10

*Primary analysis dataset

**The lower bound of the 95% confidence interval of the difference (BondEase-CWCD) is -0.13 which did not reach, but was very close to the pre-specified non-inferiority margin of -0.1.

Table 5: Summary of Secondary Endpoints (ITT Population)

	BondEase*	CWCD*
≥ 50% wound apposition at 10 days, % (n/N)	93.3% (98/105)	96.3% (52/54)
Optimal cosmesis at 28 days (score of 6), % (n/N)	70.5% (74/105)	64.8% (35/54)
Cosmesis at 28 days (all scores), mean / median	5.7 / 6.0	5.6 / 6.0

*There were no significant differences between treatment groups.

Table 6: 100% Wound Apposition at 10 Days by Subgroup (PP Population)

	100% wound apposition		BondEase-CWCD (95% CI)*
	BondEase	CWCD	
Deep dermal sutures used			
Yes, n/N (%)	63/78 (80.8%)	31/39 (79.5%)	0.01 (-0.14 – 0.17)
No, n/N (%)	11/18 (61.1%)	10/12 (83.3%)	-0.22 (-0.53 – 0.09)
Wound type			
Incision, n/N (%)	60/72 (83.3%)	32/40 (80.0%)	0.03 (-0.12 – 0.18)
Injury, n/N (%)	14/24 (58.3%)	9/11 (81.8%)	-0.24 (-0.54 – 0.07)

*There were no significant differences between treatment groups.

While investigators were paid to conduct the study, the value of compensation was not determined by the study outcome. None of the investigators had a proprietary interest or equity in the product.

Conclusions Drawn from Nonclinical and Clinical Data

The results from extensive biocompatibility, animal and bench testing and clinical study confirm that BondEase® is substantially equivalent to the predicate devices.