January 11, 2022

Milly Milly, Regulatory Affairs Consultant
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
SOUTH KOREA

Re: K211851
Trade/Device Name: Ora-Aid
Regulatory Class: Unclassified
Product Code: OLR, MGQ
Dated: June 4, 2021
Received: June 15, 2021

Dear Milly Milly:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K211851

Device Name
Intra-oral Wound Dressing

Indications for Use *(Describe)*
Intra-oral Wound Dressing is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery.
Intra-oral Wound Dressing operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing.

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 K211851**

Issue Date: June 4, 2021 (Revision Date: Jan 11, 2022)

## 1. INFORMATION

1.1 Submitter Information


- Submitter Name: TBM Corporation
- Address
  : B-301, 313, Cheomdangwagi-ro, Buk-gu, Gwangju, 61008, Korea
- Telephone Number: +82-62-971-2845
- Fax: +82-62-971-2815


1.2 Contact Person


- Name: Milly (Consultant / KMC, Inc.)
- Address: Room no. 1709, 123, Digital-ro 26-gil, Guro-gu, 08390, Republic of Korea
- Telephone Number: +82-70-8965-5554
- Fax: +82-2-2672-0579
- E-mail: milly@kmcerti.com


## 2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: Ora-Aid (Model: AD12, OB23, OB53)

2.2 Common Name: Intra-oral Wound Dressing

2.3 Classification Name: Dressing, wound and burn, hydrogel

2.4 Product Code: MGQ, OLR

2.5 Classification Regulation: Unclassified

2.6 Device Class: Unclassified

2.7 Classification Panel: Dental

## 3. PREDICATE DEVICE

| **Predicate Device** | |
|---|---|
| Manufacturer | MIZ Implants Technologies Ltd. |
| Device Name (Trade Name) | PerioPatch |
| 510(k) Number | K110750 |

## 4. SUBJECT DEVICE DESCRIPTION

Intra-oral Wound Dressing is a device comprised of an oral mucosa adhesive side and a protection side. The oral mucosa adhesive side is composed of a water soluble polymer that when exposed to moisture in the oral cavity changes into a gel state to achieve adhesion to the wound area. The protection side consists of a water-insoluble polymer which covers the wound to protect the applicable area from the environment in the oral cavity. Intra-oral Wound Dressing is simply a non-sterile bandage to protect oral wounds.

## 5. INDICATON FOR USE

Intra-oral Wound Dressing is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery. Intra-oral Wound Dressing operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing.

**6. SUBSTANTIAL EQUIVALENCE**

| - | **Subject Device** | **Predicate Device** |
|---|---|---|
| **Manufacturer** | TBM Corporation | MIZ Implants Technologies Ltd. |
| **Product Name** | Intra-oral Wound Dressing | PerioPatch |
| **Device Name** | Ora-Aid | PerioPatch |
| **510(k) Number** | K211851 | K110750 |
| **Product Code** | MGQ, OLR | MGQ, FRO |
| **Indications for Use** | Intra-oral Wound Dressing is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery. Intra-oral Wound Dressing operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing. | PerioPatch is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery. PerioPatch operates to relieve pain by adhering to and protecting affected tissues from further irritation, thereby allowing healing. |
| **Prescription or OTC** | Prescription Use | Prescription Use |
| **Mechanism of Action** | It reverts to a soft and gel-type thin sheet in the oral environment and adheres to and protects affected tissue as a physical barrier to reduce irritation and pain. | It reverts to a soft and gel-type thin sheet in the oral environment and adheres to and protects affected tissue as a physical barrier to reduce irritation and pain. |
| **Adhesion time** | 4 hours | 30 to 45 minutes |
| **Structure** | Polymer | Polymer |
| **Sterility** | None | None |
| **Single Use** | Yes | Yes |
| **Size** | AD12: 12mm x (0.3~0.399)㎜ [DxT]<br>OB23: 25mm x 15mm x (0.3~0.399)mm [WxLxT]<br>OB53: 50mm x 15mm x (0.3~0.399)mm [WxLxT] | 24mm x 8 mm x 190mm [WxLxT]<br>25mm x 8 mm x 190mm [WxLxT] |
| **Material** | Refer to Reference 1 | Refer to Reference 2 |
| 1) W (Wide) x L (Length) x T (Thickness) or D (Diameter) x T (Thickness) | | |

6.1 Material Comparative Table

| No | Reference 1<br>(Subject Device) | Reference 2<br>(Predicate Device) | Function |
|---|---|---|---|
| 1 | Povidone | Polyvinylacetate | Film former |
| 2 | Hydroxyethyl cellulose | Hydroxypropyl methylcellulose | Thickner |
| 3 | Carbomer940 | - | Thickner |
| 4 | Glycerin | - | Humectant |

| | | | |
|---|---|---|---|
| 5 | Polyethylene Glycol | - | Humectant |
| 6 | Citric Acid Hydrate | - | pH buffering agent |
| 7 | Trolamine | - | pH buffering agent |
| 8 | Sorbitan Monooleate | - | Emulsifier |
| 9 | Polysorbate 20 | - | Emulsifier |
| 10 | Ethanol | Alcohol | Solvent |
| 11 | Purified Water in Bulk | - | Solvent |
| 12 | Saccharin Sodium Hydrate | - | Sweetener |
| 13 | Methylparaben | - | Preservative |
| 14 | Tocopherol Acetate | - | Anti oxidant |
| 15 | Minty Flavor | - | Minty Flavor |
| 16 | Ethylcellulose | - | Film former |
| 17 | Castor Oil | - | Plasticizer |
| 18 | Ethanol | - | Solvent |
| 19 | Titanium Oxide | - | Opacifier |
| 20 | Poly | - | - |
| 21 | - | Natural Calcium | Unidentified |
| 22 | - | Silicon | Unidentified |
| 23 | - | Phosphorus Elements | Unidentified |

6.2 Narrative summary of the similarities and the differences between the Subject Device and the Predicate Device

The similarities and differences in comparative tabulation between the subject device (Ora-Aid) and predicate device (PerioPatch – K110750) are summarized below.

Both devices are prescription devices, consisting of a polymer type material for single use and provided non-sterile. Both devices revert to a soft and gel-type thin sheet in the oral environment and adheres to and protects affected tissue as a physical barrier to reduce irritation and pain.

In terms of technological differences, material, adhesion time and size differ between the subject device and the predicate device.

Although materials and material functions are different as found in the Material Comparable Table, Biocompatibility tests were conducted according to ISO 10993 and performance tests (Adhesion) according to EN 13726. These tests were conducted for assurance of the safety and the performance of the subject device on the materials and function.

Although the subject device is provided non-sterile, a microbial limit test was conducted according to KP11th standard that is described with the same test method as USP 40NF35 <61> and USP 40NF35 <62> to address the risk of infection to compromised oral mucosa with use of the device. The result indicates no growth was observed.

Adhesion time is different between the subject device (4hours) and the predicate device (35 ~ 45minutes) according to bench testing. Adhesion time of the subject device was noted to be longer than the predicated device. According to bench test result related to adhesion, the adhesion performance of the subject device is longer than the predicate device for protecting oral wounds.

Although the size including shape of the subject device is different from the predicate device, results of both the subject device and the predicate device are verified in accordance with bench testing and biocompatibility testing.

Overall, the differences in technological characteristics of the subject and predicate devices do not raise any different questions of safety and effectiveness.

**7. NON-CLINICAL DATA**

7.1 Safety Test

1) Biocompatibility

The biocompatibility tests were performed to protect patients from undue risks arise from biological hazards associated with materials of manufacture and final device. The tests were performed in accordance with the following standards and FDA Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

| No. | Test Items | Standards |
|---|---|---|
| 1 | Cytotoxicity | ISO 10993-5:2009 |
| 2 | Sensitization | ISO 10993-10:2010 |
| 3 | Intracutaneous Reactivity Test | ISO 10993-10:2010 |
| 4 | Acute Systemic Toxicity Test | ISO 10993-11:2016 |
| 5 | Material-Mediated Pyrogen Test | ISO 10993-11:2016 |

2) Microbial Limit Test

The microbial limit test (MLT) was performed to assess how many and which of certain microorganisms are present in this non-sterile product. The test was performed in accordance with following standards.

| No. | Test Items | Standards |
|---|---|---|
| 1 | Microbial Limit Test | USP 40NF35 <61> |
| | | USP 40NF35 <62> |
| | | USP<1111> |

3) Shelf-life Test

The shelf-life test was performed to decide expiration date and to assess a stability of physical properties of their packaging materials within the duration of the proposed shelf-life. The tests were performed in accordance with following standards.

| No. | Test Items | Standards |
|---|---|---|
| 1 | Accelerated Aging Test | ASTM F 1980 |

7.2 Performance Test

The following tests were performed to assess effectiveness of the product performance. The tests were performed in accordance with following standards.

Although the bench testing report indicate there is a difference with the physical property (adhesion) between subject device and predicate device, the difference does not raise any concerns of safety and effectiveness.

| No. | Test Items | Standards |
|---|---|---|
| 1 | Absorbency | EN 13726-1:2002 |

**8. CONCLUSION**

In comparing for substantial equivalence between the subject device and the predicate device, similarities include product code, indications for use, mechanism of action and structure. Although there are some differences

(raw material characteristics and size), the safety and performance test reports provided do not raise concerns of safety and effectiveness of the subject device in comparison to the predicate device.
In this regard, we conclude that the subject device is substantially equivalent to the predicate device.