September 18, 2019

TBM Corporation
% Ryan Hwang
Consultant
KMC, Inc.
Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu
Seoul, 08375 REPUBLIC OF KOREA

Re: K183436
Trade/Device Name: OraCure® (Model: CR12, OB23, OB53)
Regulatory Class: Unclassified
Product Code: OLR
Dated: June 14, 2019
Received: June 17, 2019

Dear Ryan Hwang:

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 post marketing 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 Adjodha
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183436

Device Name
OraCure® (Model: CR12, OB23, OB53)

Indications for Use *(Describe)*
OraCure® is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indicated for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces, and ill-fitting dentures.

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.

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510(k) SUMMARY

This summary of 510(k) –safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: December 7, 2018

1. INFORMATION

1.1 Submitter Information

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

1.2 Contact Person

- Name: DongHa Lee (Consultant / KMC, Inc.)
- Address: Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu, Seoul, 08375, Korea
- Telephone Number: +82-70-8965-5554
- Fax: +82-2-2672-0579
- E-mail: dhlee@kmcerti.com

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: OraCure® (Model: CR12, OB23, OB53)

2.2 Common Name: Oral Wound Dressing

2.3 Classification Name: dressing, wound and burn, hydrogel w/drug and/or biologic

2.4 Product Code: MGQ

2.5 Classification Regulation: Unclassified

2.6 Device Class: Unclassified

2.7 Classification Panel: General & Plastic Surgery

3. PREDICATE DEVICE

Predicate Device	
Manufacturer	Sunshine International Group, Inc.,
Device Name (Trade Name)	UlceloocinTM Oral Ulcer Patch
510(k) Number	K070842

4. SUBJECT DEVICE DESCRIPTION

OraCure® is an oral wound dressing comprising a mucous-adhesive side on a protection side, wherein the adhesive side has a strong adhesion when it is applied and hydrated on mucus. Adhesive side is water-soluble polymer that reacts with moisture (water and saliva) in the mouth within a short time and changes into a gel state. The protection side for protection of the mucous-adhesive side consists of water-insoluble polymer. The polymer on the protection side is insoluble in the water and covers the wound to protect the applicable area from the environment (bacteria, saliva, food, etc.) in the mouth. OraCure® does not contain any biological additives or drugs with respect to wound treatment, but it is simple non-sterile bandage to protect ulcer tissue.

5. INTENDED USE

OraCure® is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indicated for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces, and ill-fitting dentures.

6. SUBSTANTIAL EQUIVALENCE

-	Subject Device	Predicate Device
Manufacturer	TBM Corporation	Sunshine International Group, Inc.,
Device Name	OraCure®	UlceloocinTM Oral Ulcer Patch
510(k) Number	-	K070842
Product Code	MGQ	MGQ
Indications for Use	OraCure® is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indicated for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces, and ill-fitting dentures.	UlcerloocinTM Oral Ulcer Patch is intended for use as an oral wound dressing to protect ulcer tissue by forming a physical barrier on the wound tissue to avoid further irritation and thus to relieve pain. It is indicated for use with all types of ulcers and small wounds of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by self-biting, braces, and ill-fitting dentures.
Prescription or OTC	OTC (Over The Counter)	OTC (Over The Counter)
Mechanism	OraCure® is a vacuum-dried gel that adheres to oral mucosa. It slowly reverts to a soft and gel-type thin sheet in the oral environment while it adheres to and protects affected tissue as a physical barrier to reduce irritation and pain.	UlceloocinTM Oral Ulcer Patch is a vacuum-dried hydrogel that adheres to oral mucosa. It slowly reverts to a soft and gel-type thin sheet in the oral environment while it adheres to and protects affected tissue as a physical barrier to reduce irritation and pain.
Structure	Polymer	Polymer

Sterility	None	None
Single Use	Yes	Yes
Size	D: Diameter, T: Thickness W: Wide, L: Length ① Model No.: CR12 - Circle Shape (DxT) 1.2cm x (0.3~0.399)㎜ ② Model No.: OB23 - Rectangle Shape (WxLxT) 2.5cm x 15mm x (0.3~0.399)mm ③ Model No.: OB25 - Rectangle Shape (WxLxT) 5cm x 15mm x (0.3~0.399)mm	D: Diameter, T: Thickness ① Circle Shape (DxT) 1cm x 0.3mm

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
6	Subaccute/Subchronic Toxicity Test	ISO 10993-11:2016
7	Genetoxicity	ISO 10993-3:2014
8	Implantation	ISO 10993-6:2016

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.

No.	Test Items	Standards
1	Absorbency	EN 13726-1:2002
2	Moisture Vapour Transmission Rate	EN 13726-2:2002
3	Conformability	EN 13726-4:2003

8. CONCLUSION

Under the comparing substantial equivalence between the subject device and the predicate device, there are the same points such as product code, indications for use, mechanism and structure.
Although there are some differences (raw material characteristics and size), the safety and performance test reports are supported to the safety and effectiveness of the subject device.
In this regard, we conclude that the subject device is substantially equivalent to the predicate device.