November 27, 2019

Forward Science
Brian Pikkula, Ph.D.
President
10401 Greenbough, Ste 100
Stafford, Texas 77477

Re: K191987
Trade/Device Name: Orapeutic
Regulatory Class: Unclassified
Product Code: MGQ, OLR
Dated: July 24, 2019
Received: July 25, 2019

Dear Brian Pikkula:

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,

for Srinivas Nandkumar, Ph.D.
Acting 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

Indications for Use

510(k) Number: K191987

Device Name: **Orapeutic™ Oral Pain Gel**

Indications For Use:

Orapeutic™ Oral Pain Gel manages the pain of oral wounds, mouth sores, injuries and ulcers of the oral mucosa. It adheres to oral tissue and forms a protective barrier between the wound and further irritation & contamination. Orapeutic™ Oral Pain Gel also maintains a moist wound environment.

Prescription Use _____X_____ AND/OR Over-the-Counter _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY **K191987**

Submitted by: Forward Science LLC
10401 Greenbough, Ste 100
Stafford, TX 77477
Ph: 855-696-7254
Fax: 855-329-6725

Contact Person: Brian Pikkula, PhD

Date Prepared: November 27, 2019

Proprietary Name: Orapeutic™ Oral Pain Gel

Common Name: Dressing, Wound And Burn, Hydrogel W/Drug And/Or Biologic

Device Class: Unclassified (Pre-Amendment)

Panel: General & Plastic Surgery

Product Code: MGQ

Predicate Device: Sock It! Oral Pain Gel (K063148)

Device Description:

Orapeutic™ Oral Pain Gel is a viscous hydrogel wound dressing composed entirely of food grade ingredients including a food grade preservative system. It is designed to be physiologically compatible with both intact and compromised tissue in the mouth to manage the pain associated with injuries to the mouth.

Orapeutic Oral Pain Gel's primary mode of action for pain relief is that it adheres to the wound surface, conforms to the contours of the wound, and protects the wound from contamination and irritation by forming a protective barrier. It also maintains a moist wound environment.

Orapeutic Oral Pain Gel is provided in 10mL syringes.

Intended Use:

Orapeutic™ Oral Pain Gel manages the pain of oral wounds, mouth sores, injuries and ulcers of the oral mucosa. It adheres to oral tissue and forms a protective barrier between the wound and further irritation & contamination. Orapeutic™ Oral Pain Gel also maintains a moist wound environment.

Comparison of Technology

Orapeutic™ Oral Pain Gel and Sock It! are both hydrogels that manage the pain of oral wounds by forming a protective barrier between the wound and external environment. Both are provided as gels in ready to use syringes.

The formulations of Orapeutic™ Oral Pain Gel and Sock It! differ. The differences from the predicate does not affect the safety of the subject device because Orapeutic's components are all Food Grade with established safety profiles. The differences do not affect the efficacy of Orapeutic as demonstrated in the results of the comparative non-clinical performance testing submitted in this application.

Table 1. Comparison of Subject Device and Predicates

Comparison Parameters	*Subject Device*	*Predicate*
	Orapeutic™ Oral Pain Gel	**Sock It! (**K063148**)**
Intended Use	• Management of oral pain • Adheres to oral tissue forming a protective barrier • Provides moist environment	• Management of oral pain • Adheres to oral tissue forming a protective barrier • Provides moist environment
Area of Use	Oral Mucosa	Oral Mucosa
Applications/Day	Use as needed	Use as needed
Prescription/OTC	Prescription	Prescription & OTC
Packaging	Gel in syringe provided with cap and blunt tip	Gel in syringe provided with cap and blunt tip
Type of Product	Ready for use	Ready for use
Sterility	Non-sterile	Non-sterile

Non-clinical Performance Testing

Bench testing comparing Orapeutic™ Oral Pain Gel and Sock It! were performed. The results were substantially equivalent for Orapeutic and the predicate, providing further evidence of substantial equivalence. The testing consisted of:

- pH
- Hydrogel Barrier Testing
- Microbial Testing

Clinical Performance Testing

No clinical performance testing was conducted.

Conclusions

Based upon technologic characteristics as well as the results of comparative non-clinical performance testing, we believe that Orapeutic™ Oral Pain Gel is substantially equivalent to the predicate K063148.