December 22, 2022

Forward Science LLC
Brian Pikkula
Chief Scientific Officer
10810 Criaghead Dr
Houston, Texas 77025

Re: K221428
Trade/Device Name: PerioStom Dental Dressing
Regulatory Class: Unclassified
Product Code: OLR, MGQ
Dated: November 22, 2022
Received: November 23, 2022

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,

Michael E. Adjodha -S

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)*
K221428

Device Name
PerioStom™ Dental Dressing

Indications for Use *(Describe)*

PerioStom™ Dental Dressing is an oral wound dressing intended as a physical barrier for temporary protection of oral mucosal tissue and to provide pain relief.

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."

Forward Science LLC

10810 Craighead Dr.
Houston, TX 77025 USA
Ph: 855-696-7254

510(k) SUMMARY

Submitted by:	Forward Science LLC 10801 Craighead Dr. Houston, TX 77025 Ph: 855-696-7254 Fax: 855-329-6725
Contact Person:	Brian Pikkula, PhD
Date Prepared:	November 22, 2022
Proprietary Name:	PerioStom™ Dental Dressing
510(k) Number:	K221428
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:	HemCon® Dental Bandage (K060363)

Device Description:

PerioStom™ Dental Dressing is a powder based wound dressing comprised entirely of spray-dried chitosan. PerioStom™ Dental Dressing is provided to the clinician in a stainless steel container and can be applied to the tissue via a dental instrument of their choice (e.g. a Prichard or Howard Periosteal Elevator) or a dry gloved finger. PerioStom™ Dental Dressing is also supplied in preloaded cartridges for application to harder to reach areas of the oral mucosa via the FS Dispenser™.

Indications For Use:

PerioStom™ Dental Dressing is an oral wound dressing intended as a physical barrier for temporary protection of oral mucosal tissue and to provide pain relief.

Intended Use:

PerioStom™ Dental Dressing can be utilized for the pain relief and protection of oral mucosa due to irritation, trauma, or following iatrogenic procedures such as scaling and root planing.

Forward Science LLC

10810 Craighead Dr.
Houston, TX 77025 USA
Ph: 855-696-7254

Substantial Equivalence

PerioStom™ Dental Dressing is technologically equivalent to the predicate device, Hemcon Dental Dressing; both are dried chitosan based dressings that are applied to oral mucosal surfaces. Both devices, when exposed to saliva, blood or crevicular fluids, become a bioadherent gel acting as a physical barrier for the mucosal tissue.

PerioStom™ Dental Dressing is substantially equivalent to Hemcon Dental Dressing as evidenced in Table 1. There are no technological differences between the subject and predicate devices.

Both the subject device and the predicate consist of chitosan that when exposed to oral fluids form a protective layer over the compromised mucosa. Both PerioStom™ Dental Dressing and Hemcon Dental Dressing provide pain relief by coating damaged mucosa and protecting it from further contamination and irritation. Therefore, PerioStom™ Dental Dressing and its predicate, Hemcon Dental Dressing, are substantially equivalent.

Table 1. Comparison of Subject Device and Predicates

Comparison Parameters	*Subject Device*	*Predicate*
	PerioStom™	**HemCon Dental Bandage** (K060363)
Intended Use	oral wound dressing intended as a physical barrier for temporary protection of oral mucosal tissue and to provide pain relief	oral wound dressing intended as a physical barrier for temporary protection of oral mucosal tissue and to provide pain relief
Area of Use	Oral Mucosa	Oral Mucosa
Chemical Characteristics	Dried chitosan	Dried chitosan
Applications	Once per wound	Use as needed
Use	Single use	Single use
Prescription/OTC	Prescription	Prescription
Intended User	Dental Professional	Dental Professional
Type of Product	Ready for use	Ready for use

Non-clinical Performance Testing:

Bench testing comparing PerioStom™ Dental Dressing and Hemcon Dental Dressing were performed. The results were substantially equivalent for PerioStom and the predicate, providing further evidence of substantial equivalence. The testing consisted of:

- Viscosity
- pH
- Microbial Testing
- Wound Barrier Testing

Forward Science LLC

10810 Craighead Dr.
Houston, TX 77025 USA
Ph: 855-696-7254

Biocompatibility:

In vitro and *in vivo* biocompatibility testing according to ISO 10993 standards for Cytotoxicity, Sensitization, and Irritation/Intracutaneous Reactivity were performed. The testing demonstrated that PerioStom™ Dental Dressing met the ISO 10993 requirements for biocompatibility.

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, and *in vitro* & *in vivo* biocompatibility testing, we believe that PerioStom™ Dental Dressing is substantially equivalent to the predicate K060363.