August 5, 2026

HCS Innovation, LLC
Peter Catalano
Official Correspondent
384 Highlands Court
Union Grove, Alabama 35175

Re: K260120
Trade/Device Name: NaturaJel™ Oral Wound Care Kit
Regulatory Class: Unclassified
Product Code: OLR
Dated: July 21, 2026
Received: July 21, 2026

Dear Peter Catalano:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260120

Please provide the device trade name(s).

NaturaJel™ Oral Wound Dressing

Please provide your Indications for Use below.

NaturaJel adheres to oral mucosal tissue and forms a protective barrier over wounds or ulcers to prevent further irritation and contamination. It provides a moist wound environment required for optimal healing.

NaturaJel manages pain associated with:
- Oral mucosal wounds, sores, injuries, and ulcers
- Canker sores and cold sores
- Irritation from orthodontic appliances (braces, brackets, expanders), dentures, and partials
- Soft tissue pain from orthodontics, aphthous ulcers, and extraction sites

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY- K260120

Submitted By:	HCS Innovation, LLC 384 Highlands Union Grove, AL 35175 Ph:256-293-3755
Contact Person:	Peter Catalano, MD 617-999-2973
Date Prepared:	August 4, 2026
Proprietary Name:	NaturaJel™ Oral Wound Dressing
510(k) Number:	K260120
Common Name:	Hydrogel Oral Wound Dressing
Device Class:	Unclassified
Panel:	Dental
Product Code:	OLR, MGQ
Predicate:	OraSoothe® SockIt! (K063148)

Device Description:

NaturaJel™ is a topical gel with mushroom chitosan and sodium alginate biopolymers in sterile water. NaturaJel™ is provided in a prefilled single use syringe ready for use allowing for application directly to the tissue site or application via a dental/medical instrument of their choice (e.g. a cotton tipped swab, Hurd Elevator or similar applicator).

Indications For Use:

NaturaJel adheres to oral mucosal tissue and forms a protective barrier over wounds or ulcers to prevent further irritation and contamination. It provides a moist wound environment required for optimal healing.

NaturaJel manages pain associated with:

- Oral mucosal wounds, sores, injuries, and ulcers
- Canker sores and cold sores
- Irritation from orthodontic appliances (braces, brackets, expanders), dentures, and partials
- Soft tissue pain from orthodontics, aphthous ulcers, and extraction sites

Substantial Equivalence:

NaturaJel™ Oral Wound Dressing is similar technologically to the predicate device, OraSoothe® SockIt!: both are polysaccharide-based dressings that when applied to oral tissue provide a protective layer over compromised tissue.

Both NaturaJel Oral Wound Dressing and OraSoothe SockIt! manages pain associated with the indicated wounds or ulcers by coating damaged oral tissue and protecting the tissue from further contamination and irritation.

Bench testing performed to examine tissue adherence demonstrated substantial equivalence to the predicate device.

Table 1: Comparison of Subject Device and Predicate

Comparison Parameters	Subject Device- **NaturaJel™ Oral Wound Dressing** (K260120)	Predicate - **OraSoothe® SockIt!** (K063148)
Indications for Use	NaturaJel adheres to oral mucosal tissue and forms a protective barrier over wounds or ulcers to prevent further irritation and contamination. It provides a moist wound environment required for optimal healing. NaturaJel manages pain associated with: • Oral mucosal wounds, sores, injuries, and ulcers • Canker sores and cold sores • Irritation from orthodontic appliances (braces, brackets, expanders), dentures, and partials • Soft tissue pain from orthodontics, aphthous ulcers, and extraction sites	This product manages the pain in all types 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 and contamination. It provides the moist wound environment required for optimal wound healing. Manages pain of, for example: • All types of oral wounds, mouth sores, injuries and ulcers of the oral mucosa • Canker sores and cold sores • Irritation and traumatic ulcers such as those caused by various appliances such as braces, brackets, full and partial dentures and

		palatal expanders • Soft tissue pain from orthodontics Aphthous ulcers • Extraction site pain • Oral mucositis and stomatitis Irritation and pain following tooth scaling and prophylaxis.
Area of Use	Oral Tissue	Oral Tissue
Chemical Characteristics	Polysaccharides. The blue dye allows for visual confirmation of complete coverage.	Polysaccharides
Applications	Once per wound	Multiple per wound
Use	Single Use	Multiple use per patient
Prescription/OTC	Prescription	Prescription and OTC
Intended User	Medical/Dental Professional	Medical/Dental Professional and consumers
Type of Product	Ready for Use	Ready for Use

Non-clinical Performance Testing:

Bench testing comparing NaturaJel™ and OraSoothe® SockIT! were performed. The results were substantially equivalent for NaturaJel and the predicate, providing further evidence of substantial equivalence. The testing consisted of physical properties testing including the following:

- Viscosity
- pH
- Shear Testing for Adhesion
- Evaluation of Calcium Acetate Treatment

Biocompatibility:

In vitro and *In vivo* biocompatibility testing according to ISO 10993 standards for Cytotoxicity, Sensitization, Acute Systemic Toxicity and Irritation were performed.

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 biocompatibility testing, we believe that NaturaJel™ is substantially equivalent to the predicate K063148.