July 29, 2026

Emanate Biomedical
Jarret Fass
CEO
45 Rockefeller Plaza
19th floor
New York, New York 10111

Re: K251908
Trade/Device Name: Emanate Tray
Regulatory Class: Unclassified
Product Code: OLR
Dated: July 27, 2026
Received: July 27, 2026

Dear Jarret Fass:

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
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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.	K251908

Please provide the device trade name(s).

Emanate Tray

Please provide your Indications for Use below.

Emanate Tray is a periodontal wound dressing intended to protect injured periodontal tissue post planned non-surgical periodontal procedures by forming a temporary physical barrier to avoid further irritation.

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

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

510(k) #: K251908

510(k) Summary

Prepared on: 2026-07-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Emanate Biomedical
Applicant Address	45 Rockefeller Plaza 19th floor New York NY 10111 United States
Applicant Contact Telephone	917-709-1741
Applicant Contact	Mr. Jarret Fass
Applicant Contact Email	Jfass@emanatebiomedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Emanate Tray
Common Name	Oral Wound Dressing
Classification Name	Unclassified
Regulation Number	Pre-Amendment
Product Code(s)	OLR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K083516	Periogenix	EMA

Device Description Summary

21 CFR 807.92(a)(4)

The Emanate Tray is a single use, nonsterile, patient-matched device provided by a dental professional to their patients. The Emanate Tray device has two components: a “dental tray” component and a “hydrogel” component. The role of the dental tray is to keep the hydrogel in place while the role of the hydrogel is to physically cover the periodontal wound. Every Emanate Tray device consists of two patient-matched dental trays - one for the lower jaw and one for the upper jaw - configured during the manufacturing process to incorporate channels on the inner surface of the tray that correspond to a patient’s periodontal tissue, where wounds from planned, non-surgical periodontal treatment transpire. The channels are loaded with the hydrogel during the manufacturing process. The physical property of the hydrogel is such that it maintains its shape while yielding to pressure. Once a patient removes the tray from their mouth, the hydrogel remains in the tray and no hydrogel is left on the gingiva.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Emanate Tray is a periodontal wound dressing intended to protect injured periodontal tissue post planned non-surgical periodontal procedures by forming a temporary physical barrier to avoid further irritation.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Emanate Tray and Periogenix have the same intended use, i.e., they are both dental wound dressings intended to protect injured periodontal tissue. The Emanate Tray and Periogenix have virtually identical indications for use. Their indications for use are as follows:

--Emanate Tray Indications for Use: Emanate Tray is a periodontal wound dressing intended to protect injured periodontal tissue post planned non-surgical periodontal procedures by forming a temporary physical barrier to avoid further irritation.

--Periogenix Indications for Use: Periogenix is a periodontal wound dressing intended to protect injured periodontal tissue (gums) by forming a temporary physical barrier to avoid further irritation.

The indications for use of the devices differ slightly in that the Emanate Tray's indications for use includes "post planned non-surgical periodontal procedures", as the device is patient specific and must be manufactured for the individual patient in advance of their procedure.

Emanate Tray's indications for use fall within the intended use of the predicate device and thus, both devices have the same intended use.

Technological Comparison 21 CFR 807.92(a)(6)

Both the Emanate Tray and the predicate device consist of a dental tray with a gel used to physically cover periodontal wounds to protect them from further irritation. In both devices, a disposable dental tray is used to place and maintain the dressing against the target tissue. Both devices are worn on the maxillary and mandibular arches.

Thirty (30) disposable trays are used during the prescribed duration for both devices. Both devices are worn multiple times a day for similar durations, twice/day for Emanate and three/day for the predicate device, for at least 30 minutes.

The Emanate Tray differs from the predicate device in design as the hydrogel is pre-dispensed in the disposable tray while the predicate device is dispensed into the disposable tray by the patient prior to use. In light of the shelf-life performance testing and preservative effectiveness testing performed, whether the product is pre-dispensed or dispensed at the time of use does not raise different questions of safety and effectiveness.

While Emanate Tray uses a hydrogel as the wound dressing, the predicate device uses a paste-like gel. And while some of the materials in the subject and predicate devices are the same, others differ. The difference in materials between the Emanate Tray and the predicate device do not raise different questions of safety or effectiveness as the materials in both devices physically cover a periodontal wound, have been demonstrated to be biocompatible, and have a long history of safe use.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Test Summary:
Comprehensive non-clinical performance and shelf-life testing was conducted to demonstrate that the Emanate Tray meets its design, functional, and stability requirements. Testing included evaluation of hydrogel characteristics, CHG and p-chloroaniline (pCA) content, mechanical properties of the tray material, antibacterial resistance, preservative effectiveness, and stability following simulated shipping and accelerated aging. All studies met the established acceptance criteria and demonstrated that the device maintains its intended physical, chemical, and mechanical performance throughout the proposed three-month shelf life.

Biocompatibility Testing:
Biocompatibility testing of the final, finished Emanate Tray device was conducted in accordance with the ISO 10993 series of standards, ISO 7405, and applicable FDA's Biocompatibility Guidance. The biological evaluation included cytotoxicity, oral mucosal irritation, sensitization, acute systemic toxicity, subchronic systemic toxicity, and material-mediated pyrogenicity. In addition, a toxicological risk assessment was performed to evaluate the biological safety of the device materials. The device was found to be non-irritating to the oral mucosa, non-sensitizing, non-pyrogenic, and demonstrated no evidence of acute or subchronic systemic toxicity. The overall toxicological risk assessment demonstrated that the device is biocompatible for its intended clinical use.

Conclusions:
Based on the technological characteristics of the Emanate Tray and the results of non-clinical performance, shelf-life, and biocompatibility testing, Emanate Biomedical concludes that the Emanate Tray is as safe and effective as the legally marketed predicate device and is substantially equivalent for its intended use.