January 3, 2025

Zinkh NV
Emiel Lippens
Product manager
Zuiderlaan 1-3
PO box: 8
Gent, 9000
BELGIUM

Re: K241283
Trade/Device Name: Elemental Granulate
Regulatory Class: Unclassified
Product Code: OLR, EMA
Dated: December 23, 2024
Received: December 23, 2024

Dear Emiel Lippens:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241283

Device Name

Elemental Granulate

Indications for Use *(Describe)*

Elemental Granulate is a periodontal wound dressing intended to protect injured periodontal tissue as surgical sites.

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."

510(k) SUMMARY FOR ELEMENTAL GRANULATE

1. SUBMITTER

Zinkh NV
Zuiderlaan 1-3
Post office box 8
9000 Ghent
Belgium

Contact person: EMIEL LIPPENS
Email: EMIEL.LIPPENS@ZINKH.COM
Telephone Number: +32 478 55 37 57

Date prepared: 03 January 2025

2. DEVICE

Proprietary Name: Elemental Granulate
Classification name: Oral wound dressing
Device Classification: Unclassified and Class II following 21 CFR 872.3275
Product Code: OLR, EMA

3. PREDICATE DEVICE

Predicate device	510(k) number	Applicant
COE PAK (Auto mix, Regular or Hard set)	K881422	COE Laboratories, Inc.

4. DEVICE DESCRIPTION

Elemental Granulate is a thermoplastic and non-resorbable medical device, which under *in vitro* conditions is found to be bacteriostatic. Material consistency is plastic-like and highly moldable after heating. Hardening starts 30 to 60 seconds after taking it away from the heat source. Hardens into a rigid material after approximately 90 seconds. Individual granules may slightly differ in size. For use only by a dental professional in the recommended indications.

5. INDICATIONS FOR USE

Elemental Granulate is a periodontal wound dressing intended to protect injured periodontal tissue at surgical sites.

6. COMPARISON OF INDICATIONS FOR USE WITH THE PREDICATE DEVICE

The intended use of the device is the same as the intended use of the predicate device, since both medical devices are intended as periodontal wound dressing.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Elemental Granulate has similarities with the predicate device on aspects such as anatomical site, environmental use, performance, biocompatibility, and microbiological status resulting in a similar safety and performance profile and are both easy-to-use and moldable devices for dental (health professionals) to be used within patients requiring a periodontal wound dressing, mostly post-

surgery. Elemental Granulate differs in chemical composition, physical properties and therefore also in the preparatory handling steps. These differences are summarized in more detail below.

Feature - Technological characteristics	**Submission Device – Elemental Granulate**	**Predicate device– COE-PAK**	**Identified differences**
Human Factors	Different preparatory handling steps: • mixing within heat up water or sterile saline to approximately 90°C or 194°F by stirring with a non-plastic tool; and • reworking can be done by re-heating.	Different preparatory handling steps: • mixing with a spatula and/or a mixing tip; and • tackiness of the mixture needs to be checked and therefore lubrication of the fingers might be required.	Similar, for Elemental Granulate there is no need to test the tackiness, which is needed for the predicate device. All other steps are comparable between the devices.
Material and design	Thermoplastic polymer with antibacterial additive granules, free of (zinc oxide-)eugenol, to ensure respectively the moldability when used in combination with water or sterile saline solution of approximately 90°C or 194°F and bacteriostatic properties (ISO 22196).	A reaction between a catalyst (fluid paste; metallic oxide or more specific zinc oxide) and a base (paste; fatty acid), which contains non-viable biological-derived ingredients (plant-derivates), to ensure a moldable mixture.	Similar. For COE-PAK a reaction between metallic oxide and fatty acid is needed to ensure a moldable mixture, while Elemental Granulate becomes moldable by heating.
Compatibility with other products	For the dental health professional and within the preparatory handling, it is important to not use plastic and to wear personal protective equipment, whereby it may stick and therefore latex gloves and/or wetting the gloves are recommended. For the intended patient population, it is important to note that a slight discoloration of the material might take place in the patient's mouth due to food consumption or use of antiseptics.	No specific instructions other than that COE-PAK should be used by a dental professional only.	Similar between the devices, but for Elemental Granulate it was decided to provide a more detailed instruction related to compatibility with other products.

8. NON-CLINICAL TESTING

The following non-clinical performance and safety testing were conducted to support the substantial equivalence with the predicate device:

- Biocompatibility assessment and testing was conducted in conformity to ISO 10993 standards, including a toxicological risk assessment per ISO 10993-17.
- Test report according to ISO 22196 to demonstrate the antibacterial activity on Elemental Granulate.
- Evaluation of plastics potency to inhibit oral biofilm formation, malodor, or decrease viability of oral pathobionts.
- Test report to show a reduction in total biofilm by making use of Elemental Granulate in comparison to other dental materials, while the (proliferation of) humans cells are not affected.
- Theoretical summative evaluation resulting in a usability engineering risk assessment.

9. CLINICAL TESTING

Clinical testing, although available, was not needed in support of this 510(k) application.

10. CONCLUSIONS

Based on similarity in technology and the same indication for use as well as the results of performance testing, Elemental Granulate is substantially equivalent to the predicate device COE-PAK. Therefore, the subject device is safe and effective as the predicate device that has been legally marketed in the United States.