January 10, 2025

Overfibers S.r.l.
Castrenze Genovese
Company Representative
Via Malatesta,7
Imola (BO), 40026
ITALY

Re: K242366
Trade/Device Name: OverCEM SA Universal; OverCEM SA Translucent; OverCEM SA Opaque; OverCEM Ti-Abutment; OverCEM Cer-Abutment
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: August 9, 2024
Received: December 11, 2024

Dear Castrenze Genovese:

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)*

K242366

Device Name

OverCEM SA Universal;
OverCEM SA Translucent;
OverCEM SA Opaque;
OverCEM Ti-Abutment;
OverCEM Cer-Abutment

Indications for Use *(Describe)*

1. Definitive cementation of inlays, onlays, crowns and bridges, in ceramic or zirconia, composite or metal; 2-3 unit Maryland bridges and 3-unit inlay/onlay bridges (to be avoided for patients with bruxism or periodontitis).
2. Definitive cementation of endocanal posts.
3. Definitive cementation of ceramic, zirconia, composite or metal restorations on implant abutments and natural teeth.
4. Definitive cementation of zirconium oxide superstructures for two-unit abutments

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.

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510(k) Summary – K242366

1. Contact Details:

Applicant Name:	Overfibers S.r.l.
Applicant Address:	Via Malatesta, 7 Imola (BO) 40026, Italy
Applicant Contact Telephone:	+39 345 5002938
Applicant Contact:	Castrenze Genovese
Applicant Contact Email:	ezio.genovese@overfibers.com
Date Prepared:	11/12/2024

2. Device Name:

Device Trade Name:	OverCEM SA Universal; OverCEM SA Translucent; OverCEM SA Opaque; OverCEM Ti-Abutment; OverCEM Cer-Abutment.
Common Name:	Dental cement
Classification Name:	Cement, Dental
Regulation Number:	872.3275
Product Code(s):	EMA

3. Legally Marketed Predicate Devices

Product	Applicant	510(k) No.	Code No	Predicate	Decision Date
G-CEM ONE	GC America Inc.	K200798	EMA	Primary	11/24/2020

4. Device Description Summary

OverCEM is dual-curing, self-adhesive resin luting cement. The components consists of Paste A and B, which are filled in a one-body syringe. Both pastes are automixed with a mixing tip. The operating principle of the device is based on two reactions, one self-curing and one light-curing. OverCEM is designed to strongly and stably connect reconstruction materials and endocanal posts to patients' teeth or implants.

5. Intended Use/Indications for Use

1. Definitive cementation of inlays, onlays, crowns and bridges, in ceramic or zirconia, composite or metal; 2-3 unit Maryland bridges and 3-unit inlay/onlay bridges (to be avoided for patients with bruxism or periodontitis).
2. Definitive cementation of endocanal posts.
3. Definitive cementation of ceramic, zirconia, composite or metal restorations on implant abutments and natural teeth.
4. Definitive cementation of zirconium oxide superstructures for two-unit abutments

6. Package:

1. Refill OverCEM SA
OverCEM SA syringe (Universal/Translucent/Opaque) 9,5 g (1), T-Mixer regular (8), T-Mixer wide (5) and endo-tip (5).

2. Refill OverCEM Abutment
OverCEM Abutment syringe (Ti-Abutment/Cer-Abutment) 9,5 g (1), T-Mixer regular (13).

3. Starter Kit OverCEM SA
- OverCEM SA syringe (Universal+Translucent+Opaque) 9,5 g (3), T-Mixer regular (24), T-Mixer wide (15) and endo-tip (15);
- OverCEM SA syringe (Universal) 9,5 g (3), T-Mixer regular (24), T-Mixer wide (15) and endo-tip (15);
- OverCEM SA syringe (Translucent) 9,5 g (3), T-Mixer regular (24), T-Mixer wide (15) and endo-tip (15);
- OverCEM SA syringe (Opaque) 9,5 g (3), T-Mixer regular (24), T-Mixer wide (15) and endo-tip (15).

4. Starter Kit OverCEM Abutment:
- OverCEM Abutment syringe (Ti-Abutment) 9,5 g (3), T-Mixer regular (30);
- OverCEM Abutment syringe (Cer-Abutment) 9,5 g (3), T-Mixer regular (30).

7. Shelf life and storage condition

- Shelf life 2 year;
- Recommended for optimal performance, store at temperature of 2-25°C (36.0-77.0°F). Avoid exposure of the cement to direct bright light or humidity during cement application to avoid setting time shortening.

8. Performance Bench Tests

The device has been tested according to ISO 4049:2009 - Dentistry – Polymer-based restorative materials, ISO 13116:2015 - Dentistry - Test Method for Determining Radio-Opacity of Materials, ISO 7491:2000 - Dental materials — Determination of colour stability and ISO 29022:2013 - Dentistry — Adhesion — Notched-edge shear bond strength test.
Performance testing includes:
- Diametral tensile strength
- Film thickness
- Compression strength

- Working time
- Setting time
- Flexural strength
- Water sorption
- Solubility
- Color stability
- Radio-Opacity
- Adhesive bond strength

9. Non-Clinical Performance Testing

A biocompatibility assessment was completed according to ISO 10993-1:2021, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
With reference to the ISO 10993-1 standard, medical devices belonging to the OverCEM family are classified as: externally communicating, tissue/bone/dentin contact devices for a permanent contact duration (>30 days).

The tests performed are:

- In vitro cytotoxicity based on the criteria of the protocol of ISO 10993-5:2009
- Skin sensitisation based on the criteria of the protocol of ISO 10993-10:2010
- Intracutaneous reactivity based on the criteria of the protocol of ISO 10993-10:2010

In conclusion, biocompatibility of OverCEM is acceptable device from the biological evaluation result.

10. Clinical Performance Testing

No clinical testing has been performed on this device.

11. Comparison of Technology

The applicant and predicate device have the same polymerisation methods.
The raw materials used by the predicate device are substantially equivalent to those of the applicant.
The applicant and predicate device are the same in function, and similar in composition and intended use.
This supports that the compatibility of the applicant device is substantially equivalent to the predicate devices.

12. Differences

The OverCEM device, unlike the predicate device, is a self-adhesive resin luting cement with dual-curing (self-curing and light-curing), without the use of a second component (the predicate device needs the combination G-CEM ONE and G-CEM ONE ADHESIVE ENHANCING PRIMER for self-curing).

	Applicant Device (K242366)	Primary predicate (K200798)
Trade name	OverCEM SA Universal OverCEM SA Translucent OverCEM SA Opaque OverCEM Ti-Abutment OverCEM Cer-Abutment	G-CEM ONE
Manufacturer	Overfibers S.r.l.	GC Corporation
Prescription/over-the-counter use	Prescription Use	Prescription Use
Product category	Dual-curing, self-adhesive resin luting cement.	Self-adhesive resin cement
Paste/paste ratio	Paste A / Paste B = 1.0 (w/w)	Paste A / Paste B = 1.3 / 1.0 (w/w)
Indication for Use	1. Definitive cementation of inlays, onlays, crowns and bridges, in ceramic or zirconia, composite or metal; 2-3 unit Maryland bridges and 3-unit inlay/onlay bridges (to be avoided for patients with bruxism or periodontitis). 2. Definitive cementation of endocanal posts. 3. Definitive cementation of ceramic, zirconia, composite or metal restorations on implant abutments and natural teeth. 4. Definitive cementation of zirconium oxide superstructures for two-unit abutments	1. Cementation of all types of all ceramic, resin and metal-based inlays, onlays, crowns and bridges. 2. Cementation of metal, ceramic, fiber posts, and cast post and cores. 3. Cementation of all ceramic and composite veneers. 4. Final cementation of crowns and bridges on implant abutments.
Product description	The components consists of Paste A and B, which are filled in a one-body syringe. Both pastes are automixed with a mixing tip. The operating principle of the device is based on two reactions, one self-curing and one light-curing. OverCEM is designed to strongly and stably connect reconstruction materials and endocanal posts to patients' teeth or implants.	The components consist of Paste A and B, which are filled in a one-body syringe. Both pastes are automixed with a mixing tip and directly applied to restorations or the prepared cavity.
Instruction for use	1. Tooth preparation; 2. Preparation of the root canal; 3. Restoration preparation; 4. Dispensing; 5. Cementation; 6. Excess cement removal; 7. Final checks; 8. Final polishing.	1. Tooth preparation 2. Application of G-CEM ONE ADHESIVE ENHANCING PRIMER (Optional) 3. Restoration preparation 4. Dispensing 5. Cementation 6. Excess cement removal 7. Final set 8. Final polishing

Curing specification	**Light cure** using a light curing unit: - 20-30 sec (>1000mW/cm^2 lamp) **Self-curing**: - 35°C/95°F: o Working time: 01:30 o Setting time: 04:00 - 23°C/73.4°F: o Working time: 03:00 o Setting time: 06:00	**Light cure** using a light curing unit. - 10 sec. (High Power LED Light) (>1200mW/cm2) - 20 sec. (Halogen/LED) (700 mW/cm2) **Self-curing**: G-CEM ONE can be combined with the dedicated Adhesive Enhancing Primer (AEP). This innovative Primer induces what we call "touch cure mechanism" for an accelerated and very effective dark-cure (self-cure) reaction of G-CEM ONE.
Comparison of technology	Methacrylates contained in Paste A polymerize by polymerization initiators contained in Paste A and Paste B. In addition, they also polymerize by light irradiation with photo polymerization initiators contained in Paste A. For self-curing, working and setting times are influenced by storage temperature, environment and oral temperature. The curing of OverCEM SA slows down considerably at room temperature and accelerates in the oral cavity. OverCEM SA is a dual material and therefore sensitive to daylight and artificial light. The working time is reduced if it is used under a white light operating lamp: reduce the light intensity to avoid unwanted polymerisation. Methacrylates contained in this material are very hydrophobic and set material is stable. Therefore, the ingredients in the cured material are difficult to elute in water. Flexural Strength [MPa]: 102.25 Film Thickness [µm]: 23.10 Setting Time [s]: 240 declared in the IFU (200.40 test result) Working Time [s]: 90 Water sorption [µm/mm^3]: 45 Water solubility [µm/mm^3]: 0.883 Color stability: Excellent overall behaviour in colour stability tests	Methacrylates contained in Paste A polymerize by polymerization initiators contained in Paste A and Paste B. In addition, they also polymerize by light irradiation with photo polymerization initiators contained in Paste A. Furthermore, using G-CEM ONE ADHESIVE ENHANCING PRIMER for the cavity and abutment tooth, surface modification and cement polymerization are promoted and hardened with the cement. Methacrylates contained in this material are very hydrophobic and set material is stable. Therefore, the ingredients in the cured material are difficult to elute in water. Flexural Strength [MPa]: 150 Film Thickness [µm]: 5 Setting Time [s]: 240 Working Time [s]: 165 Water sorption [µm/mm^3]: 0.0000025 Water solubility [µm/mm^3]: 0.0000016 Color stability: Excellent colour stability Regarding the adhesion strength, the following results are obtained for different substrates: • Dentin [MPa]: 9.24 ± 2.06 • Enamel [MPa]: 26.45 ± 7.72 • Zirconia ceramic [MPa]: 32.45 ± 3.09

	Regarding the adhesion strength, the following results are obtained for different substrates: • Dentin [MPa]: 12.95 ± 2.22 • Enamel [MPa]: 29.62 ± 7.75 • Zirconia ceramic [MPa]: 44.21 ± 6.53 • Glass Ceramic [MPa]: 31.40 ± 5.68 • Composite [MPa]: 31.27 ± 3.51 • Metal [MPa]: 34.84 ± 4.97 The OverCEM devices are radio-opaque.	• Glass Ceramic [MPa]: 19.55 ± 5.06 • Composite [MPa]: 22.85 ± 4.77 • Metal [MPa]: 29.34 ± 4.71 There is no information on the radio-opacity of the device. The data on the properties of the device were taken from the documentation that the manufacturer made available on its website and from the scientific literature. Data for adhesion strength were obtained from a test performed by Overfibers S.r.l according to ISO 29022:2013.

13. Conclusion

Based on similarities in intended use, mode of action, chemical composition, and performance testing, OverCEM, is substantially equivalent to the primary predicate device G-CEM ONE (K200798).