



April 15, 2026

Inter-Med, Inc.
Alex Johnson
VP of Engineering, Regulatory & Quality
2200 S. St.
Racine, Wisconsin 53404

Re: K253337
Trade/Device Name: REGEN Bioactive Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: September 26, 2025
Received: September 30, 2025

Dear Alex Johnson:

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.

K253337

?

Please provide the device trade name(s).

?

REGEN Bioactive Cement

Please provide your Indications for Use below.

?

Designed for luting of indirect restorations (inlays, onlays, crowns, bridges, and endodontic posts) made of metal alloys, composite resins, porcelain, lithium disilicate or zirconia.

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)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Inter-Med, Inc.
Applicant Address	2200 South St Racine WI 53404 United States
Applicant Contact Telephone	262-631-5306
Applicant Contact	Mr. Alex Johnson & Mr. Dominic Egizi
Applicant Contact Email	ajohnson@vista-dental.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	REGEN Bioactive Cement
Common Name	Dental cement
Classification Name	Cement, Dental
Regulation Number	872.3275
Product Code(s)	EMA

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210259	Parkell Self-Adhesive Cement	EMA

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

REGEN Bioactive Cement is a bioactive luting cement with a dual-cure system, anerobic self-polymerization and photopolymerization, designed to create a durable and permanent bond between dentin or enamel and indirect restorations such as dentures and crowns. While bonded to the tooth, REGEN Bioactive Cement releases calcium and phosphate.

Five (5) grams of each component (base paste and catalyst paste) are packaged into a foil-sealed dual-barrel syringe totaling 10 grams of product mass. This device is for prescription use (Rx) only.

This is the only 510(k) for this medical device, no prior 510(k)s have been submitted.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

Designed for luting of indirect restorations (inlays, onlays, crowns, bridges, and endodontic posts) made of metal alloys, composite resins, porcelain, lithium disilicate or zirconia.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are the same.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Similarities between the subject device (REGEN Bioactive Cement) and the predicate device (Parkell Self-Adhesive Cement).

- REGEN Bioactive Cement has identical indications for use as its predicate device (Parkell Self-Adhesive Cement).
- REGEN Bioactive Cement is classified under product code EMA, with respect to 21 CFR 872.3820 and the common name “self-adhesive resin cement”, which is identical to that of the predicate device (Parkell Self-Adhesive Cement).
- REGEN Bioactive Cement has identical intended population use as the predicate device (Parkell Self-Adhesive Cement) and is used in the same anatomical location.
- Identical to the predicate device (Parkell Self-Adhesive Cement), REGEN Bioactive Cement is a two-component self-adhesive resin device capable of self-polymerization and photopolymerization.
- REGEN Bioactive Cement uses an identical mechanism of action for its indications compared to the predicate device (Parkell Self-Adhesive Cement), namely, both materials utilize monomers polymerized through a radical-release mechanism to provide structural and adhesive function, and radiopacity to indirect restorations.
- Identical to the predicate device (Parkell Self-Adhesive Cement), REGEN Bioactive Cement is classified as an external communicating device for permanent (>30 days) contact per ISO 7405:2018.
- REGEN Bioactive Cement composition consists of similar ingredients to the predicate device (Parkell Self-Adhesive Cement).
 - o Any differences in composition do not raise any concerns as biocompatibility testing confirms the product is biocompatible for its intended use.
- Identical to the predicate device (Parkell Self-Adhesive Cement), REGEN Bioactive Cement is a dual-component, non-aqueous paste-like material that is commercialized as non-sterile. Both the subject device and predicate device are stored in dual barrel syringes and are applied through identical mixing tips.
- Identical to the predicate device (Parkell Self-Adhesive Cement), REGEN Bioactive Cement is for prescription use (Rx) only.

This is the only 510(k) for this medical device, no prior 510(k)s have been submitted.

Discussion of Differences between the subject device (REGEN Bioactive Cement) and the predicate device (Parkell Self-Adhesive Cement).

- The formulation of REGEN Bioactive Cement is slightly different than the predicate device (Parkell Self-Adhesive Cement).
 - o The differences in composition do not raise any concerns as biocompatibility testing (ISO 10993-5:2009 cytotoxicity testing) and benchtop testing (510(k) Section Benchtop testing) confirms the product is substantially equivalent to the predicate device.
 - o Therefore, the subject device remains substantially equivalent to its predicate device despite differences in composition.
- REGEN Bioactive Cement is stored differently than Parkell Self-Adhesive Cement.
 - o A heat-sealed foil pouch is used with REGEN Bioactive Cement to promote long term stability of the product. Parkell Self-Adhesive Cement syringes are not stored with a secondary seal, instead placed directly into a box. The addition of a foil pouch as another packaging layer is not considered a significant change and substantial equivalence to the predicate device is maintained.
- REGEN Bioactive Cement’s predicted shelf life of 15 months is shorter than the predicate device’s (Parkell Self-Adhesive Cement) stated shelf life of 24 months.
 - o This difference is not considered significant as the expiration of dental products varies widely in the field. As all products maintain an expiration date on their labeling, this information is sufficiently communicated to users.
 - o Therefore, the subject device remains substantially equivalent to its predicate device despite differences in composition.

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

The following non-clinical tests were conducted to evaluate the functionality, performance, safety, and substantial equivalence of REGEN Bioactive Cement to the predicate device (Parkell Self-Adhesive Cement):

- Real-Time Shelf-Life Summary
 - o Given the available data for REGEN Bioactive Cement, a room-temperature shelf-life of 15 months is assigned.
- Setting Time and Flowability
 - o This test confirms that REGEN Bioactive Cement conforms to the ISO 4049 set time requirements for Class 3 devices of no longer than 10 minutes and matches Parkell Self-Adhesive Cement’s claim of sub-5-minute self-cure. Therefore, the subject device is substantially equivalent to the predicate device in terms of set time.
- Flexural Strength
 - o The formulation of REGEN Bioactive Cement “passed” the test criteria of ISO 4049 and provided results that support a substantial equivalence designation of the subject device to the predicate device Parkell Self-Adhesive Cement.
- Water Sorption and Solubility
 - o The formulation of REGEN Bioactive Cement “passed” the test criteria of ISO 4049 and provided results that support a substantial equivalence designation of the subject device to the predicate device Parkell Self-Adhesive Cement.
- Shear Bond Testing
 - o REGEN Bioactive Cement “passed” the test criteria and provided results that were substantially equivalent to the predicate device, Parkell Self-Adhesive Cement.
- Film Thickness

o REGEN Bioactive Cement "passed" the test criteria and provided results that were substantially equivalent to the predicate device, Parkell Self-Adhesive Cement.

- Polymerized Shrinkage

o REGEN Bioactive Cement yielded shrinkage results in line with the predicate device, Parkell Self-Adhesive Cement. Therefore, the subject device is substantially equivalent to the predicate device in terms of shrinkage.

- Radiopacity

o REGEN Bioactive Cement is concluded to be equivalent to Parkell Self-Adhesive Cement in terms of radiopacity. Therefore, substantial equivalence is supported.

- Cytotoxicity

o REGEN Bioactive Cement yielded substantially equivalent cytotoxicity results compared to the predicate device (Parkell Self-Adhesive Cement).

- Transit Testing

o This testing confirmed REGEN Bioactive Cement's packaging is robust and passed simulated transit testing parameters.

- Phosphate and Calcium Ion Release

o REGEN Bioactive Cement's claim of Calcium and Phosphate ion release is verified. The test results support a substantial equivalence designation of the subject device to the predicate device (Parkell Self-Adhesive Cement).

Clinical testing was not deemed necessary for this 510(k).