April 2, 2024

Dentsply Sirona
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K240888
Trade/Device Name: Calibra Abutment Resin Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental cement
Regulatory Class: Class II
Product Code: EMA
Dated: March 30, 2024
Received: April 1, 2024

Dear Dave Yungvirt:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Calibra Abutment Resin Cement

Indications for Use *(Describe)*
Calibra Abutment Resin Cement is indicated for the cementation of:

Extraoral assembly of prosthetic components, e.g., structures made of ceramic or zirconia onto custom or pre-fabricated titanium/titanium alloy or zirconia bases/implant inserts/abutments, e.g., InCoris ZI and CEREC Tessera™ Abutment Block prostheses and mesostructures to TiBases.

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.

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K240888

510(k) SUMMARY for
Calibra Abutment Resin Cement

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Rebecca Sporer
Telephone Number: 717-849-4793
Email: Corporate-RA@dentsplysirona.com

Date Prepared: 20 March 2024

2. Device Name:
   - Proprietary Name: Calibra Abutment Resin Cement
   - Classification Name: Dental Cement
   - CFR Number: 872.3275
   - Device Class: Class II
   - Product Code: EMA

3. Predicate/Reference Devices:

Predicate Device Name	510(k)	Company Name
Multilink Hybrid Abutment Cement	K130436	Ivoclar Vivadent

Reference Device Name	510(k)	Company Name
Self-Adhesive Resin Cement	K073173	Dentsply Sirona

4. Description of Device:
   Calibra Abutment Resin Cement is a two-component, self-cure, high strength self-adhesive cement.

   Calibra Abutment Resin Cement has the ability to bond to titanium and is chemically compatible with silanated ceramic materials, making it suitable for extraoral assembly of prosthetic components. This self-cure only, opaque shade has been optimized for extraoral assembly when blocking of metal graying or show-through is desired.

   Cured Calibra Abutment Resin Cement is essentially hydrophobic, minimizing post-cure water sorption, solubility and hygroscopic expansion.

5. Indications for Use:
   Calibra Abutment Resin Cement is indicated for the cementation of:

   Extraoral assembly of prosthetic components, e.g., structures made of ceramic or zirconia onto custom or pre-fabricated titanium/titanium alloy or zirconia bases/implant inserts/abutments, e.g., InCoris ZI and CEREC Tessera™ Abutment Block prostheses and mesostructures to TiBases.

6. Technological Comparison:
   Calibra Abutment Resin Cement incorporates similar fundamental technology (principle of operation, material form, mixing ratio, polymerization method, and delivery system) as the predicate device, Multilink Hybrid Abutment cement (K130436). Calibra Abutment Resin Cement incorporates similar fundamental technology (differ in polymerization method) and is similar in formulation to the reference device Self-Adhesive Resin Cement (K073173). The reference device Self-Adhesive Resin Cement (K073173) is being incorporated for comparison to shelf-life and biocompatibility. The proposed Calibra Abutment Resin Cement is available in one shade, opaque, when compared to the predicate and reference devices which are available in more than one shade.

7. Non-Clinical Tests Summary and Conclusion:
   Test data to verify the performance of the proposed Calibra Abutment Resin Cement has been provided including work time, set time, film thickness, consistency, flexural strength and bond strength to multiple prosthetic components. The results show that the proposed device meets the requirements of the non-clinical bench testing conducted to support substantial equivalence.

   A biological risk assessment was conducted on the proposed device, Calibra Abutment Resin Cement, upon the review of available information on raw materials, manufacturing processes, chemical characterization tests and existing preclinical biological testing data. Overall, when considering the full complement of results available, this risk assessment indicates that the likelihood of a toxic effect from the proposed device, Calibra Abutment Resin Cement, is low.

8. Clinical Tests Summary and Conclusion:
   Not applicable.

9. Substantial Equivalence:

Table 9.1 compares the indications for use of the proposed device, Calibra Abutment Resin Cement, to the predicate device, Multilink Hybrid Abutment Cement (K130436).

Table 9.1-Comparison of Indications For Use between the proposed and the predicate devices

Proposed Device Calibra Abutment Resin Cement	**Predicate Device Multilink Hybrid Abutment Cement (K130436)**	**Comparison Discussion**
Calibra Abutment Resin Cement is indicated for the cementation of: Extraoral assembly of prosthetic components, e.g., structures made of ceramic or zirconia onto custom or pre-fabricated titanium/titanium alloy or zirconia bases/implant inserts/abutments, e.g., InCoris ZI and CEREC Tessera™ Abutment Block prostheses and mesostructures to TiBases	Multilink Hybrid Abutment Cement is indicated for extraoral, permanent cementation of ceramic structures made of lithium disilicate glass ceramic	The proposed Calibra Abutment Resin Cement and the predicate device, Multilink Hybrid Abutment Cement (K130436) are both indicated for the extraoral assembly of appliances.

10. Conclusion Regarding Substantial Equivalence:
    Calibra Abutment Resin Cement is a dental cement which is intended for the extraoral cementation assembly of prosthetic components. Calibra Abutment Resin Cement has the same intended use, incorporates the same fundamental technology and has similar indications for use as the predicate Multilink Hybrid Abutment cement (K130436). Calibra Abutment Resin Cement incorporates similar fundamental technology and is similar in formulation to the reference device Self-Adhesive Resin Cement (K073173). Test data to verify the performance of the proposed Calibra Abutment Resin Cement has been provided including work time, set time, film thickness, consistency, flexural strength and bond strength to multiple prosthetic components. The results of this testing, combined with the design comparison with the predicate device Multilink Hybrid Abutment Cement (K130436) and the reference device Self-Adhesive Resin Cement (K073173), support substantial equivalence.