August 5, 2026

Dental Manufacturing S.p.A.
℅ Celline Souza Lakus
Submitter / Official Correspondent
Ruthinium USA
2365 Chesterfield Dr.
Kronenwetter, Wisconsin 54455

Re: K261456
Trade/Device Name: Ruthinium Disc
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: POW, EBG
Dated: May 1, 2026
Received: May 1, 2026

Dear Celline Souza Lakus:

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.	K261456

Please provide the device trade name(s).

Ruthinium Disc

Please provide your Indications for Use below.

The Ruthinium Disc is a polymethyl methacrylate (PMMA) blank intended for use in CAD/CAM systems for the fabrication of long-term temporary crowns and bridges, until permanent restorations can be delivered.

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

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

5. 510(k) SUMMARY

K261456

5.1. Submitter Information *(807.92(a)(1))*

510(k) Owner / Applicant:		Dental Manufacturing S.p.A. Via Cà Mignola Nuova 1699 Badia Polesine (RO), Italy, 45021 Phone: +39 0425 51628	
Contact Person / Official Correspondent:		Celline Souza Lakus 2365 Chesterfield Dr Kronenwetter, WI 54455 Phone: +1 715 348 9720 Email: souzacelline@gmail.com	
Date Prepared:	May 1st, 2026	**Date Revised:**	August 5th, 2026

5.2. Device Identification *(807.92(a)(2))*

Trade Name:	Ruthinium Disc
Common Name:	PMMA CAD/CAM Disc
Classification Name:	Temporary Crown and Bridge Resin
Regulation Number:	21 CFR 872.3770
Product Code:	EBG
Device Class:	Class II

5.3. Predicate Devices *(807.92(a)(3))*

The subject device is substantially equivalent to the following legally marketed devices:

Primary Predicate Device:	K172281 – PuRE PMMA Disc

5.4. Device Description *(807.92(a)(4))*

The Ruthinium Disc is a pre-polymerized polymethyl methacrylate (PMMA) CAD/CAM disc intended for use in the fabrication of long-term temporary crowns and bridges.

The device is manufactured from cross-linked, high-molecular-weight PMMA resin combined with pigments to provide the desired shade and esthetic characteristics. The Ruthinium Disc family includes monolayer, multilayer, and multilayer SC configurations.

The monolayer configuration consists of a uniform shade throughout the disc. The multilayer configuration incorporates gradual shade layering intended to provide a natural esthetic appearance. The multilayer SC configuration incorporates a gradient between enamel and dentin layers.

Differences among the configurations are limited to pigmentation and shade-layering characteristics. The base PMMA material, intended use, manufacturing process, and fundamental technological characteristics are the same across the device family.

The device is supplied in disc form for use with compatible CAD/CAM milling systems. It is provided non-sterile and is intended for prescription use.

5.5. Intended Use / Indications for Use *(807.92(a)(5))*

The Ruthinium Disc is a polymethyl methacrylate (PMMA) blank intended for use in CAD/CAM systems for the fabrication of long-term temporary crowns and bridges, until permanent restorations can be delivered.

The intended use and indications for use are the same as those of the predicate devices.

5.6. Technological Characteristics Comparison *(807.92(a)(6))*

The Ruthinium Disc and the predicate device, PuRE PMMA Disc, K172281, have the same intended use and similar fundamental technological characteristics. Both devices are PMMA-based CAD/CAM discs supplied non-sterile for the fabrication of long-term temporary crowns and bridges.

The devices are similar with respect to:

General Material Composition:	PMMA with pigments
Manufacturing Process:	Heat-cured polymerization
Device Form:	CAD/CAM disc
Sterility:	Non-sterile
Application:	Fabrication of long-term temporary crowns and bridges

The subject device differs from the predicate device in certain non-proprietary technological characteristics, including its specific material formulation, pigment system, available shade configurations, and certain mechanical and physical properties. The Ruthinium Disc family also

includes monolayer, multilayer, and multilayer SC configurations that provide different esthetic layering effects.

These differences do not alter the intended use or fundamental scientific technology of the device and do not raise different questions of safety or effectiveness. Mechanical and physical testing conducted in accordance with ISO 10477 demonstrated that the subject device met the applicable acceptance criteria for polymer-based crown and bridge materials. Biocompatibility testing and toxicological evaluation further supported the substantial equivalence of the material for its intended use.

Accordingly, the identified technological differences do not adversely affect the safety or effectiveness of the subject device and do not preclude a determination of substantial equivalence.

Non-Clinical Performance Data *(807.92(b)(1))*

Non-clinical performance testing was conducted to support the substantial equivalence of the Ruthinium Disc.

Mechanical and Physical Testing:	Mechanical and physical testing was conducted in accordance with ISO 10477. The testing demonstrated that the subject device met the applicable acceptance criteria for polymer-based crown and bridge materials.
Biocompatibility:	The biological safety of the subject device was evaluated in accordance with the ISO 10993 series of standards. The evaluation included the following tests: • Cytotoxicity; • Sensitization; and • Irritation. The results of the biocompatibility testing supported a determination of substantial equivalence for the subject device in terms of biological safety.
Chemical and Toxicological Evaluation:	Chemical characterization and toxicological risk assessment were conducted in accordance with applicable portions of ISO 10993-17 and ISO 10993-18. The results supported substantial equivalence of the subject device in chemical and toxicological safety.

No clinical data were required to support substantial equivalence.

5.7. Clinical Performance Data *(807.92(b)(2))*

Clinical data were not required for this submission.

5.8. Conclusion *(807.92(b)(3))*

The Ruthinium Disc has the same intended use and similar fundamental technological characteristics as the predicate device, PuRE PMMA Disc, K172281.

Differences between the subject device and predicate device, including differences in specific material formulation, pigments, shade configurations, and certain mechanical or physical properties, do not raise different questions of safety or effectiveness.

The results of mechanical and physical testing, biocompatibility testing, chemical characterization, and toxicological risk assessment demonstrate that the subject device is as safe and effective as the predicate device.

Therefore, the Ruthinium Disc is substantially equivalent to the predicate device, **PuRE PMMA Disc (K172281)**.