April 23, 2026

Mmtech Projetos Tecnologicos Importacao E Exportacao Ltda.
% Fabio Rahal
Regulatory Affairs Specialist
Passarini Regulatory Affairs of America, LLC
10185 Henbury St.
Orlando, Florida 32832

Re: K260152
Trade/Device Name: Smart Print Bio Vitality
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBI, PZY
Dated: January 20, 2026
Received: March 25, 2026

Dear Fabio Rahal:

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
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OHT1: Office of Ophthalmic, Anesthesia,
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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.	K260152

Please provide the device trade name(s).

SMART PRINT BIO VITALITY

Please provide your Indications for Use below.

Smart Print Bio Vitality is a light-curable resin intended for the fabrication of definitive dental restorations. The material can be used to produce single crowns, veneers, inlays, onlays, and artificial teeth for dental prostheses. It is also suitable for the production of removable definitive full dentures, as well as individual and removable monolithic full and partial dentures in dental offices and laboratories. The product is indicated for anterior and posterior restorations, providing an alternative to conventional restorative materials in both clinical and laboratory settings.

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)

510(k) #: K260152

510(k) Summary

Prepared on: 2026-04-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MMTECH PROJETOS TECNOLOGICOS IMPORTACAO E EXPORTACAO LTDA.
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SMART PRINT BIO VITALITY (A2, A3, BL1, B1, A2-HT, A3-HT, BL1-HT, B1-HT)
Common Name	Tooth shade resin material
Classification Name	Material, Tooth Shade, Resin
Regulation Number	872.3690
Product Code(s)	EBF, EBI, ELM

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222623	Digital Crown	EBF

Device Description Summary

21 CFR 807.92(a)(4)

Smart Print Bio Vitality is a light-cured, methacrylate-based resin intended for use in 3D printers for the production of permanent dental restorations, including crowns, inlays, onlays, veneers, and artificial teeth. It is designed exclusively for professional dental use and requires a validated CAD/CAM manufacturing workflow to ensure accuracy and reliability. The resins are intended to be used by Clinicians (licensed dentists or dental technicians) in dental offices.

The workflow begins with a digital intraoral scan, which is processed using commonly available dental CAD software to generate an industry-standard STL dataset. This dataset defines the final shape and contour of the intended restoration. The resin is then processed in compatible 3D printers equipped with a 385-405 nm light source, with recommended printing parameters of 50 µm or 100 µm layer

thickness and validated curing energy. Post-curing is performed outside the oral cavity using specialized light-curing units to ensure full polymerization and mechanical performance.

The Subject device consists of methacrylate resins, inorganic fillers, dental glass fillers, photo initiators, and pigments. These materials are well established in the dental industry for both fixed and removable prosthetic applications, due to their proven physicochemical, mechanical, and biocompatible properties.

Restorations manufactured with Smart Print Bio Vitality are available in a variety of tooth-colored shades (A2, A3, B1, and BL1 all available in classical and high translucency shades) to allow for esthetic integration with the patient's dentition. Once fabricated, the restorations are cleaned, finished, and verified chairside by the clinician for fit and function before delivery to the patient.

The resins are designed to meet the requirements of ISO 10477 and ISO 4049 and were assessed for flexural strength, water sorption, radiopacity, print accuracy/dimensional stability, color stability, material stability, and biocompatibility, ensuring long-term durability and safety for permanent use in the oral cavity

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Smart Print Bio Vitality is a light-curable resin intended for the fabrication of definitive dental restorations. The material can be used to produce single crowns, veneers, inlays, onlays, and artificial teeth for dental prostheses. It is also suitable for the production of removable definitive full dentures, as well as individual and removable monolithic full and partial dentures in dental offices and laboratories. The product is indicated for anterior and posterior restorations, providing an alternative to conventional restorative materials in both clinical and laboratory settings.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both the subject and predicate device are indicated for use in producing crowns, veneers, and artificial teeth for dental prostheses, removable definitive full dentures, and individual and removable monolithic full and partial dentures. The subject device is additionally indicated for inlays and onlays, which is typical for similar devices to the subject device.

The word "restorations" was used as a generic expression for applications described in the Indications for Use for the subject device. Despite the use of different wording, the subject device and the predicate device have identical Indications for use.

Technological Comparison

21 CFR 807.92(a)(6)

The Smart Print Bio Vitality device is a light-curable acrylate resin designed for use with 3D printing systems employing CAD/CAM technology. Similar to the predicate devices, the resin is processed through additive manufacturing, in which digital scans of the patient's oral cavity are used to fabricate definitive dental restorations. After printing, the material undergoes light-based curing to achieve its final properties, followed by cleaning and finishing steps.
At a high level, both the subject and predicate devices share the same fundamental technological principles:
- They are based on photocurable acrylate resin formulations.
- They are used in conjunction with 3D printers that rely on digital imaging.
- They undergo light curing before final trimming, finishing, and polishing.
- They are intended for the fabrication of permanent dental restorations.

Differences between the subject and predicate devices are limited to variations in resin composition, which do not alter the intended use, technological principle, or safety and effectiveness of the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following non-clinical testing data were provided in support of the substantial equivalence determination.
The biocompatibility evaluation for Smart Print Bio Vitality was conducted in accordance with ISO 10993-1 and ISO 7405, as recognized by FDA and international regulatory authorities. The battery of testing included:
- Genotoxicity
- Cytotoxicity
- Acute Systemic Toxicity
- Sensitization
- Irritation

Additional bench testing was performed according to ISO 10477 and ISO 4049, the following parameters were assessed:
- Flexural Strength and Modulus
- Water Sorption and Solubility
- Radio-opacity
- Print Accuracy and Dimensional Stability

• Shape Capability
• Color Stability and Shade Consistency
• Material Stability (Shelf-life)

The comparative analysis demonstrates that the Smart Print Bio Vitality device presents indications for use, composition, and technological principles substantially equivalent to the predicate device Digital Crown (SprintRay, K222623). Differences between the subject and predicate devices are limited to variations in resin composition, which do not alter the intended use, technological principle, or safety and effectiveness of the device. The non-clinical testing, including biocompatibility, shelf-life validation and performance testing, supports that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate.