June 30, 2026

Zima International Inc., dba Dandy
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K262195
Trade/Device Name: Dandy Ceramic Stain and Glaze
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: June 29, 2026
Received: June 29, 2026

Dear Prithul Bom:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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.	K262195

Please provide the device trade name(s).

Dandy Ceramic Stain and Glaze

Please provide your Indications for Use below.

For use in prosthetic dentistry to create an all-ceramic prosthesis.
• Ceramic for coverage of a zirconia substructure

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) #: K262195

510(k) Summary

Prepared on: 2026-06-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zima International Inc., dba Dandy
Applicant Address	22 Cortlandt Street, 30th Floor New York NY 10007 United States
Applicant Contact Telephone	717-348-0937
Applicant Contact	Mr. Nolan Shenai
Applicant Contact Email	nolan.shenai@meetdandy.com
Correspondent Name	QRS Solutions LLC
Correspondent Address	966 E 2050 N North Ogden UT 84414 United States
Correspondent Contact Telephone	(801) 440-9082
Correspondent Contact	Ms. Aubrey Meacham
Correspondent Contact Email	ameacham@qrssolutionsllc.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Dandy Ceramic Stain and Glaze
Common Name	Porcelain powder for clinical use
Classification Name	Powder, Porcelain
Regulation Number	872.6660
Product Code(s)	EIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K250673	CERABIEN MiLai	EIH

Device Description Summary

21 CFR 807.92(a)(4)

Dandy Ceramic Stain and Glaze is a porcelain powder for clinical use intended for use in professional dental laboratories. The product is a solvent based ceramic ink formulation designed to deliver coloration and characterization as applied onto zirconia dental restorations.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

For use in prosthetic dentistry to create an all-ceramic prosthesis.
• Ceramic for coverage of a zirconia substructure

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both the subject and predicate devices have the same indications for use in prosthetic dentistry to create all-ceramic prostheses. The subject device is indicated for coverage of zirconia substructures, while the predicate device additionally includes coverage of lithium disilicate substructures. This difference does not change the intended use and does not raise new questions of safety or effectiveness

Technological Comparison 21 CFR 807.92(a)(6)

The subject device, Dandy Ceramic Stain and Glaze, has the same fundamental technological characteristics as the predicate device, CEREBIAN MiLai. Both devices are ceramic stain/glaze materials applied to a ceramic substructure and subsequently fired to produce a fused, glass-based ceramic layer.

The devices share the same intended use, indications for use and principle of operation. Both use aluminosilicate glass and inorganic metal oxide pigments sourced from the same supplier. Both products are applied onto zirconia dental restorations to deliver controlled coloration and a final glaze layer. After firing, both the predicate and the subject device result in a glass based ceramic coating on the zirconia restoration.

Differences between the devices, such as the unfired physical form (pre-mixed liquid stain/glaze vs. powder-and-liquid system) and the application workflow, do not introduce new materials or new technological characteristics.

Based on these similarities in design, material composition and principle of operation the subject device has the same technological characteristics as the predicate device, and the identified differences do not raise new questions of safety or effectiveness.

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

Radioactivity testing and chemical solubility testing were performed in accordance with ISO 6872:2024 requirements for Type I Class I ceramic materials. The subject device met the applicable acceptance criteria, confirming that the device does not pose a radiological safety concern and does not adversely impact chemical solubility performance.

Flexural strength and coefficient of thermal expansion (CTE) testing were also performed to evaluate whether application of the fired stain and glaze coating affects the mechanical or thermal behavior of the zirconia substrate. These tests demonstrated that the stain and glaze coating does not adversely impact zirconia performance.

No additional ISO 6872 mechanical or physical property testing was conducted because the fired stain and glaze function as a thin ceramic surface coating, not as a bulk or structural ceramic material. The coating does not contribute to the load-bearing performance of the restoration, and the underlying zirconia substrate provides all mechanical strength. The testing performed represents the ISO 6872 elements that are scientifically applicable and clinically relevant for this device type.

Validation testing for the inkjet printer used to apply the stain and glaze was also completed, including IQ, OQ, and PQ, confirming that the automated application process operates consistently within specification.

N/A

The nonclinical testing submitted in this 510(k) supports that the subject device is as safe and as effective as the predicate device.

Radioactivity testing performed in accordance with ISO 6872:2024 demonstrated that the subject device meets the activity-concentration limit for Type I Class I dental ceramics.

Chemical solubility testing performed in accordance with ISO 6872:2024 also met the applicable acceptance criteria, confirming that the fired stain and glaze surface does not adversely impact material stability or biocompatibility.

Flexural strength and coefficient of thermal expansion (CTE) testing were conducted to evaluate whether application of the stain and glaze affects the mechanical or thermal behavior of the zirconia substrate.

These tests demonstrated that the stain and glaze coating does not adversely impact zirconia performance and meets the predefined acceptance criterion of no adverse impact to the zirconia crown.The testing performed represents the ISO 6872 elements that are scientifically applicable and clinically relevant for this device type. All results met the acceptance criteria and raise no new questions of safety or effectiveness.

Validation testing for the inkjet printer used to apply the stain and glaze, including IQ, OQ, and PQ, confirmed that the automated application process meets its defined specifications. The validation demonstrated consistent color output (≤ 1/4 VITA deviation), complete surface coverage within the validated volumetric deposition window, and acceptable viscosity performance throughout the

validated shelf life.