December 14, 2022

Zirkonzahn srl
Sandra Leitner
Regulatory Affairs Responsible
Via An der Ahr 7
Gais, BZ 39030
Italy

Re: K213722
Trade/Device Name: ICE Ceramics, ICE Stains, Fresco
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: November 10, 2022
Received: November 14, 2022

Dear Sandra Leitner:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE.
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

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)*
K213722

Device Name
ICE Ceramics, ICE Stains and Fresco

Indications for Use *(Describe)*
ICE CERAMICS, ICE CERAMICS TISSUE, ICE CERAMICS DENTINE +, ICE CERAMICS DYNAMIC DENTINE, FRESCO ENAMEL, FRESCO GINGIVA, FRESCO, FRESCO DENTINE + and FRESCO DYNAMIC DENTINE are type I ceramics for coating, staining and glazing dental restorations made of final-sintered zirconia. They are conceived for patients who require dental restorations in zirconia, such as single crowns, bridges, inlays, onlays or veneers.

ICE STAINS, ICE STAINS PRETTAU®, ICE STAINS GLAZE FLUO and ICE STAINS 3D are type I ceramics for coating, staining and glazing dental restorations made of final-sintered zirconia. They are conceived for patients who require dental restorations in zirconia, such as single crowns, bridges, inlays, onlays or veneers.

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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Section 05
510(k) Summary - K213722

510(k)
Summary

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DATE SUMMARY PREPARED: December 13, 2022

DEVICE IDENTIFICATION

Trade/Proprietary Name:	ICE Ceramics, ICE Stains and Fresco
Regulation Number:	21 CFR 872.6660
Common Name:	Powder, Porcelain
Classification Name:	Porcelain Powder for Clinical use
Class:	II
Product Code:	EIH
Panel:	Dental

LEGALLY MARKETED PREDICATE DEVICE

Company:	Zirkonzahn srl
Device Name:	Zirkonzahn Ice
Product Code:	EIH
510(k) Number:	K061851

INDICATIONS FOR USE

ICE CERAMICS, ICE CERAMICS TISSUE, ICE CERAMICS DENTINE +, ICE CERAMICS DYNAMIC DENTINE, FRESCO ENAMEL, FRESCO GINGIVA, FRESCO, FRESCO DENTINE + and FRESCO DYNAMIC DENTINE are type I ceramics for coating, staining and glazing dental restorations made of final-sintered zirconia. They are conceived for patients who require dental restorations in zirconia, such as single crowns, bridges, inlays, onlays or veneers.

ICE STAINS, ICE STAINS PRETTAU®, ICE STAINS GLAZE FLUO and ICE STAINS 3D are type I ceramics for coating, staining and glazing dental restorations made of final-sintered zirconia. They are conceived for patients who require dental restorations in zirconia, such as single crowns, bridges, inlays, onlays or veneers.

DEVICE DESCRIPTION

All devices included in this submission are dental glass ceramics. There are different device types from three device groups:

ICE Ceramics Group:

- ICE Ceramics
- ICE Ceramics Tissue
- ICE Ceramics Dentine +
- ICE Ceramics Dynamic Dentine

ICE Stains Group:

- ICE Stains
- ICE Stains Prettau®
- ICE Stains 3D
- ICE Stains Glaze Fluo

Fresco Group:

- Fresco
- Fresco Gingiva
- Fresco Enamel
- Fresco Dentine +
- Fresco Dynamic Dentine

The above mentioned devices are supplied in form of powders or pastes and are available in different colors and/ or in different quantity sizes. The users can choose among the different options according to their requirements and preferences. Furthermore specific accessories are supplied to optimize the working procedure:

ICE BUILD UP LIQUID is an accessory used for mixing of ICE CERAMICS, ICE CERAMICS TISSUE, ICE CERAMICS DENTINE + and ICE CERAMICS DYNAMIC DENTINE.
FRESCO LIQUID and FRESCO GEL are accessories used to change the viscosity of FRESCO ENAMEL, FRESCO GINGIVA, FRESCO, FRESCO DENTINE + and FRESCO DYNAMIC DENTINE products.

ICE STAIN LIQUID is an accessory used to freshen up ICE STAINS und ICE STAINS PRETTAU®; REFRESHING LIQUID 3D is an accessory used to freshen up ICE STAINS 3D; REFRESHING LIQUID GLAZE FLUO is an accessory used to freshen up ICE STAINS GLAZE FLUO.

All these devices are used by specifically trained personnel to manufacture customized dental restorations.

DISCUSSION OF NON CLINCAL TESTS

Non clinical testing was performed to determine the physical properties of the subject device. Performance testing was conducted in accordance with the International Standard ISO 6872 and the results show that the devices are well suited for their intended use. Furthermore, biocompatibility was established in according to ISO 10993-1 and ISO 10993-5.

COMPARISON TABLE

Devices	New Devices: ICE Ceramics, ICE Stains and Fresco K213722	Predicate devices: Zirkonzahn Ice K061851	Comparison
Company	Zirkonzahn srl	Zirkonzahn srl	
Product Code	EIH	EIH	Same
Regulation Number	872.6660	872.6660	Same
Regulation Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Same
Indications for use	ICE CERAMICS, ICE CERAMICS TISSUE, ICE CERAMICS DENTINE +, ICE CERAMICS DYNAMIC DENTINE, FRESCO ENAMEL, FRESCO GINGIVA, FRESCO, FRESCO DENTINE + and FRESCO DYNAMIC DENTINE are type I ceramics for coating, staining and glazing dental restorations made of final-sintered zirconia. They are conceived for patients who require dental restorations in zirconia, such as single crowns, bridges, inlays, onlays or veneers. ICE STAINS, ICE STAINS PRETTAU®, ICE STAINS GLAZE FLUO and ICE STAINS 3D are type I ceramics for coating, staining and glazing dental restorations made of final-sintered zirconia. They are conceived for patients who require dental restorations in zirconia, such as single crowns, bridges, inlays, onlays or veneers.	Metal free single posterior crowns, multiple unit anterior crowns/bridges, inlays, onlays bonded dental restorations.	Similar Zirkonzahn Ice contains a system of devices (including zirconia blanks, coloring liquids), not only dental ceramics, but the new as well as the predicate devices are intended to veneer / individualize dental frameworks.
Sizes of dental frameworks	All, dependent on zirconia device where applied	All, dependent on zirconia device where applied	Same

Chemical composition	Glass ceramic, other metallic oxides, with pigments	Glass ceramic, other metallic oxides, with pigments	Similar
Biocompatibility	ISO 10993-1 ISO 10993-5	Not specified in K061851	Similar
Tested according to ISO 6872	Flexural strength ≥ 50 MPa Chemical solubility < 100 µg/cm^2	Flexural strength ≥ 50 MPa Chemical solubility < 100 µg/cm^2	Similar
Classification acc. to ISO 6872	Type 1, class 1b	Type 1, class 1b	Same
Principles of Operation	The devices can be applied in several layers on final-sintered zirconia structures followed by firing processes. Subsequently, the dental structures are finalized by manual grinding and polishing.	The devices can be applied in several layers on final-sintered zirconia structures followed by firing processes. Subsequently, the dental structures are finalized by manual grinding and polishing.	Same
Shades	Dentine shades (Vita dentine shades A1 –D4 etc.) Intensive colors Glazes	Dentine shades (Vita dentine shades A1 –D4 etc.) Intensive colors Glazes	Similar
Form	Powders, pastes and liquids	Powders, pastes and liquids	Same

Storage Conditions	In tightly sealed original packaging with a maximal temperature of 35 °C for ICE Stains, Fresco and accessory liquids. If stored too cold, the liquid may freeze and must be defrosted before use. If stored too warm, the pastes may dry out.	Storage temperature between 10 °C and 30 °C	Differences do not have an effect on final medical device, therefore difference not significant.

SUBSTANTIAL EQUIVALENCE DISCUSSION

The new devices and the predicate devices are similar in function, chemical composition and intended use. The differences noted do not raise any new questions about safety and effectiveness. Therefore, Zirkonzahn concludes that the proposed devices are substantially equivalent to the predicate.