



June 5, 2025

esthetic ceram ag
% Anna Pocsai
Consultant
novineon CRO
Friedrich-Miescher-Straße 9
Tuebingen, Baden-Württemberg 72076
Germany

Re: K251084

Trade/Device Name: zirkon; structure; LFU shades, stains and glazes
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 9, 2025
Received: April 9, 2025

Dear Anna Pocsai:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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,

 Bobak
Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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

Submission Number (if known)

K251084

Device Name

zirkon; structure; LFU shades, stains and glazes

Indications for Use (Describe)

Types of restorations:
1. Anterior and posterior crowns
2. Veneers, inlays, onlays.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Confidential

Dental Ceramics
Abbreviated Premarket Notification [510(k)]
estetic ceram AG

K251084
510(k) Summary

This summary of 510(k) for the subjective device equivalence information is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

Date summary prepared: May 06, 2025

Applicant information:

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Contact person:

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Tel: +49707198979204
Contact person and title: Anna Pocsai, Consultant
E-mail: anna.pocsai@novineon.com

Subject device

Trade name: zirkon; structure; LFU shades, stains and glazes
Common Name: dental ceramic
Product code: EIH
FDA Regulation: 21 CFR 872.6660 – Porcelain Powder for Clinical Use
Device classification: Class II

Predicate device

Device name: Soprano 10©, Soprano©
510(k) number: K192551

1. Device Description

zirconia layering porcelain system layering ceramic powders and pastes are used in dental laboratories by the dental technician to create ceramic restorations.

2. Indications for use

Types of restorations:

1. Anterior and posterior crowns
2. Veneers, inlays, onlays.

3. Comparison to Predicate Devices

The legally marketed device to which estetic ceram is claiming equivalence is identified as Soprano 10, Soprano surface and Soprano, manufactured by Cendres+Metaux SA, Switzerland. The Soprano system consists of layering ceramics for dental restorations.

Specifically, equivalence is claimed between the following products:

- PFZ zirkon and Soprano10
- structure und stains LFU and Soprano Surface
- Stains, shades & glaze LFU and Soprano

Substantial equivalence is based on intended use, technological characteristics, material composition, and conformity with consensus standards, as described the tables below:

	Subject device	Predicate device
Product name	PFZ zirkon	Soprano 10
Manufacturer	estetic ceram AG	Cendres+Métaux SA
Indications for use	Types of restorations: 1. Anterior and posterior crowns 2. Veneers, inlays, onlays.	<ul style="list-style-type: none"> • Veneers • Inlays and onlays • Partial crowns • 3-pontic bridge in anterior tooth region • 3-pontic bridge in the premolar region up to max. 2nd premolar as a permanent abutment • Anterior and posterior tooth crowns
Technical Characteristics		
Physical state	Powder	Powder
Material	Silicate glass ceramics, Main constituents: SiO ₂ , Al ₂ O ₃ , K ₂ O, Na ₂ O, CaO, B ₂ O ₃	Silicate glass ceramic mainly composed of SiO ₂ , Al ₂ O ₃ , Li ₂ O, P ₂ O ₅ , K ₂ O, CaO, B ₂ O ₃
Classification acc to 6872:2019	Type 1 Class 1b	Type 1 Class 1b

3.1. structure

	Subject device	Predicate device
Product name	structure, LFU shades, stains and glazes	Soprano (surface)
Manufacturer	estetic ceram AG	Cendres+Métaux SA
Indications for use	Types of restorations: 1. Anterior and posterior crowns 2. 3. Veneers, inlays, onlays.	<ul style="list-style-type: none"> • Veneers • Inlays and onlays • Partial crowns • Anterior and posterior tooth crowns
Technical Characteristics		
Physical state	Powder or paste	Powder or paste
Material	Silicate glass ceramics, Main constituents: SiO ₂ , Al ₂ O ₃ , K ₂ O, Na ₂ O, Li ₂ O, B ₂ O ₃	Silicate glass ceramic mainly composed of SiO ₂ , Al ₂ O ₃ , Li ₂ O, P ₂ O ₅ , K ₂ O, CaO, B ₂ O ₃

Confidential

Dental Ceramics
Abbreviated Premarket Notification [510(k)]
estetic ceram AG



	Subject device	Predicate device
Product name	structure, LFU shades, stains and glazes	Soprano (surface)
Classification acc to 6872:2019	Type 1 Class 1b	Type 1 Class 1b

3.2. Bench Testing

This 510(k) submission includes performance testing supporting compliance to International Standard ISO 6872:2015 as recognized by FDA. Measured parameters in a representative sample of the products included:

- Flexural strength
- Chemical Solubility
- Coefficient of Thermal Expansion
- Glass Transition Temperature, and
- Radioactivity of 238U.

The results show product compliance to the requirements of ISO 6872:2015.

The subject devices is surface contacting material with contact with the oral mucosa with contact duration of more than 30 days (permanent contact). Biocompatibility evaluation was performed according to ISO 7405:2018 and ISO 10993:2018.

4. Conclusions

zirconia layering porcelain system has been demonstrated to be substantially equivalent to the predicate device.