November 22, 2019

Zirkonzahn srl
Sandra Leitner
Regulatory Affairs
Via An der Ahr 7
Gais, 39030 ITALY

Re: K190518
Trade/Device Name: Color Liquid, Vita Liquid
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: October 21, 2019
Received: October 24, 2019

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,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190518

Device Name
Zirkonzahn COLOUR LIQUID

Indications for Use *(Describe)*
Zirkonzahn COLOUR LIQUID is used for coloring pre-sintered zirconia structures.

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

K190518

510 (k)
SUMMARY

APPLICANT

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Date Summary Prepared: November 22, 2019

DEVICE IDENTIFICATION

Trade/Proprietary Name:	Zirkonzahn COLOUR LIQUID
Generic / Common Name:	Liquid for Dental Zirconia Prosthesis
Regulation Number:	872.6660
Classification Name:	Porcelain powder for clinical use
Class:	II
Product Code:	EIH
Panel:	Dental

LEGALLY MARKETED PREDICATE DEVICE

Company: The Argen Corporation
Device Name: ArgenZ Liquid Shade, Argen Z Incisal Effect, ArgenZ Color Modifier, ArgenZ Pontic Reducer
Product Code: EIH
510(k) Number: K182833

INDICATIONS FOR USE

Zirkonzahn COLOUR LIQUID is used for coloring pre-sintered zirconia structures.

DEVICE DESCRIPTION

Zirkonzahn COLOUR LIQUID devices are used for coloring milled and finished pre-sintered zirconia structures. Coloring is performed by dipping the framework into the liquid or by using a metal-free brush. Afterwards, the structure is dried and subsequently sintered at temperatures above 1400 °C.
The Zirkonzahn COLOUR LIQUIDS are available in different colors and in different bottle sizes (20 ml, 50 ml, 100 ml).
The following colors are included in this submission:

VITA tooth shades	A1, A2, A3, A3,5, A4 B1, B2, B3, B4 C1, C2, C3, C4 D2, D3, D4 1M1, 1M2 2L1.5, 2M2 3M2, 3M3 4M2
VITA Bleach shades	0M1, 0M2, 0M3
ZZ Intensive shades	Tissue A, Tissue B, Tissue C Orange 1, Brown 2 Incisal grey, Incisal violet, Incisal blue LuNe A-Cervical, B-Cervical, C-Cervical, D-Cervical
ZZ Special liquids	Translucent Opaque Fluorescence

The devices are used in the dental field by specialized technicians only.

DISCUSSION OF NON CLINICAL TESTS

Non-clinical testing was performed to evaluate the physical properties of colored zirconia compared to untreated zirconia, to demonstrate that the subject device does not negatively impact the functionality of the zirconia. The results show that the devices are well suited for their intended use.

Furthermore, to establish the shelf life and storage conditions of the subject devices, real time aging was performed (including evaluation of color, workability and appearance) according to Zirkonzahn internal test protocols.

Biocompatibility was established in consideration of the International Standard 10993-1:2010 'Biological Evaluation of Medical Devices' Part 1: Evaluation and Testing. Zirkonzahn performed biocompatibility testing for representative mixtures and Worst Case mixtures of the subject devices or established biocompatibility through evaluation of the respective substances. Therefore Zirkonzahn divided the Colour Liquid devices into 6 different groups:

Colour Liquid groups	Biocompatibility
Main group	Tested on representative mixtures: - "lamelle COLOUR LIQUID" - "Campioni realizzati in polvere di zirconia (Prettau Zirkon) infiltrate con un liquido" Tested on Worst Cases: - Worst Case 1 - Worst Case 2 - Worst Case 3
Colour Liquid Aquarell Bio-Pigment	Evaluated
Colour Liquid Prettau Aquarell – Translucent	Evaluated
Colour Liquid Prettau Aquarell – Opaque	Evaluated
Thinner	Evaluated
Stabilizer	Evaluated

SUBSTANTIAL EQUIVALENCE

	Zirkonzahn COLOUR LIQUID (new devices)	ArgenZ Liquids (K182833)	Comparison
Company	Zirkonzahn srl	The Argen Corporation	
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	Zirkonzahn COLOUR LIQUID is used for coloring pre-sintered zirconia structures.	ArgenZ Liquids are intended to be used by trained dental technicians as an accessory for shading ArgenZ frameworks and ArgenZ allzirconia, monolithic restorations for anterior and posterior dental prosthetics.	Similar
Chemical Composition	Aqueous solutions of transition and lanthanoid metal salts	Aqueous solutions of transition and lanthanoid metal salts	Similar
Biocompatibility	Established	Established	Same
Principles of Operation	Brushing or Dipping Technique	Brushing or Dipping Technique	Same
Type of Packaging and Volume	Bottle; 20 ml, 50 ml, 100 ml	Bottle; 30 ml, 100 ml	Similar
Shade	Various, including A1-D4	Various, including A1-D4	Similar
Storage Conditions	Max. 25 °C 5 years	25 - 75 °C 2 years	Minor difference

The table above provides a detailed comparison of the submitted devices and the predicate devices. Both devices are liquids used for coloring pre-sintered zirconia structures. They only slightly differ in their storage conditions. However, Zirkonzahn evaluated the storage conditions for the Zirkonzahn COLOUR LIQUID devices with real life functional testing and concluded that these indications are appropriate. Therefore, Zirkonzahn concludes that this difference can be rated as minor.

CONCLUSION

Based on the available information, the new devices and the predicates are similar in function, production technology and intended use. Therefore, we conclude that the proposed devices are substantially equivalent to the predicate.