July 8, 2020

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

Re: K200676
Trade/Device Name: ABRO 1, RESITON GINGIVA, PRIME and THERAPON TRANSPA
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG, EBI, MQC
Dated: April 7, 2020
Received: April 9, 2020

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 “Nandu” Nandkumar, Ph.D.
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)*
K200676

Device Name
ABRO 1, RESITON GINGIVA, PRIME and THERAPON TRANSPA

Indications for Use *(Describe)*
PRIME is used for manufacturing provisional crowns and bridge frameworks with up to two adjacent pontics in the anterior and posterior tooth area.
ABRO 1 is intended for the fabrication of denture teeth; RESITON GINGIVA is intended for the fabrication of denture bases.
PRIME TRANSPA, ABRO 1 TRANSPA and THERAPON TRANSPA are designed for the creation of bite splints, orthodontic splints and occlusal splints for bruxism.

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

510 (k) SUMMARY

510(k) number: K200676

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DATE PREPARED 2020-06-29

DEVICE IDENTIFICATION

Trade/Proprietary Name:	ABRO 1, RESITON GINGIVA, PRIME and THERAPON TRANSPA
Generic / Common Name:	Dental polymer blanks (discs)
Regulation Number:	872.3770
Classification Name:	Temporary crown and bridge resin
Class:	II
Primary Product Code:	EBG
Secondary Product Codes:	EBI, MQC
Panel:	Dental

LEGALLY MARKETED PRIMARY PREDICATE DEVICE

Company:	UNION DENTAL S.A.
Device Name:	IDODENTINE blanks
Primary Product Code:	EBG
Secondary Product:	EBI, MQC
510(k) Number:	K150432

LEGALLY MARKETED REFERENCE DEVICE

Company:	ZIRKONZAHN SRL
Device Name:	THERAPON
Primary Product Code:	EBG
510(k) Number:	K180562

INDICATIONS FOR USE

PRIME is used for manufacturing provisional crowns and bridge frameworks with up to two adjacent pontics in the anterior and posterior tooth area.
ABRO 1 is intended for the fabrication of denture teeth; RESITON GINGIVA is intended for the fabrication of denture bases.
PRIME TRANSPA, ABRO 1 TRANSPA and THERAPON TRANSPA are designed for the creation of bite splints, orthodontic splints and occlusal splints for bruxism.

DEVICE DESCRIPTION

The subject devices are blanks used in dental CAD/CAM milling systems by professional dental technicians to manufacture dental restorations. The devices are supplied in form of solid discs.
All devices are composed of the same basic material, Polymethylmethacrylate (PMMA), and are available in various models that differ in color and dimension.
The materials used for the submitted devices have a long history of safe use for the same or equivalent indications.

DISCUSSION OF NON CLINICAL TESTS

Zirkonzahn carried out performance testing on its devices according to ISO 10477:2018. All tested samples meet the requirements of the standard and show similar values as the predicate device.
Biocompatibility was established in consideration of the International Standard 10993-1:2010 'Biological Evaluation of Medical Devices' Part 1: Evaluation and Testing.

PREDICATE DEVICE COMPARISON TABLE

In the following comparison table, the most important aspects that support substantial equivalence to the primary predicate device are indicated.

	New devices: ABRO 1, RESITON GINGIVA, PRIME and THERAPON TRANSPA (K200676)	**Primary Predicate Device: IDODENTINE blanks (K150432)**	**Comparison**
Company	Zirkonzahn srl	UNION DENTAL S.A.	N.A.
Product Code	EBG, EBI, MQC	EBG, EBI, MQC	Same
Regulation Number	872.3770	872.3770	Same
Regulation Name	Temporary crown and bridge resin	Temporary crown and bridge resin	Same
Indications for use	PRIME is used for manufacturing provisional crowns and bridge frameworks with up to two adjacent pontics in the anterior and posterior tooth area. ABRO 1 is intended for the fabrication of denture teeth; RESITON GINGIVA is intended for the fabrication of denture bases. PRIME TRANSPA, ABRO 1 TRANSPA and THERAPON TRANSPA are designed for the creation of bite splints, orthodontic splints and occlusal splints for bruxism.	Temporary anterior and posterior crowns Temporary anterior and posterior bridges with up to two adjacent pontics Implant supported temporary restorations Maximum recommended usage period: 12 months Removable structures for dentures (dental bases) Removable structures for therapeutic restorations (bite splints or occlusal splints).	Similar (see discussion hereunder)

Chemical Composition	PMMA based with approx. 1% pigments.	PMMA >99% wt. Pigments <1% wt.	Same
Biocompatibility	Established	Established	Same
Models	Different shapes for different milling systems; different heights; different dental shades	Different shapes for different milling systems; different heights; different dental shades	Same
Shelf life	10 years	None	Different (see discussion hereunder)
Physical Properties	According to ISO 10477:2018	According to ISO 10477:2004	Same
Flexural Strength	≥ 105 MPa	IDODENTINE MULTILAYER: 83 MPa IDODENTINE TRANSPA: 94 MPa	Similar (see discussion hereunder)
Water absorption	≤ 24 µg/mm³	IDODENTINE MULTILAYER: 22.3 µg/mm³ IDODENTINE TRASPA: 25.8 µg/mm³	Similar (see discussion hereunder)
Water solubility	≤ 0.3 µg/mm³	IDODENTINE MULTILAYER: 0.7 µg/mm³ IDODENTINE TRANSPARENT: 0.9 µg/mm³	Similar (see discussion hereunder)
Residual monomer content (according to ISO 20795)	Resiton Gingiva: 0.71 wt% Therapon Transpa: < 5.0 wt%	1.4 %	Similar (see discussion hereunder)

DISCUSSION OF DIFFERENCES AND SIMILARITIES

The subject devices and the primary predicate devices are very similar in the above mentioned aspects. They share the same product codes, regulation number and regulation name, basic chemical composition and available product models. For both devices, biocompatibility was established and physical properties were tested according to ISO 10477.

The indications for use are not identical, but very similar. PRIME as well as the

predicate devices are intended to fabricate crowns and bridges. Zirkonzahn uses the term provisional, while the predicate uses the term temporary. These two terms are often used interchangeably. Both mean that the dental structure is not definitive and thus the usage period will come to an end. This difference is considered as non-significant.

The bridges made of the new device and the predicate are limited to two adjacent pontics. This indication is the same for both compared products.

The predicate blanks can be used for implant supported temporary restorations. This is also true for the new devices, also if not explicitly stated. Union Dental limits this use to 12 months. The dental structures of Zirkonzahn resins must be checked every year by the dentist, who decides whether they can remain in the mouth of the patient or not. Therefore, it is ensured that Zirkonzahn resin structures are not longer in the mouth of the patient as useful.

The new devices as well as the Idodentine blanks can be used for the production of dental prostheses. For this use, usually gingiva and tooth shaded devices are used. In case of Zirkonzahn devices, ABRO 1 and RESITON GINGIVA are used.

The predicate as well as the new devices are used for the creation of bite splints, orthodontic splints and occlusal splints for bruxism. For this use, usually transparent devices are used. In case of Zirkonzahn devices, THERAPON TRANSPA, ABRO 1 TRANSPA and PRIME TRANSPA are used.

The physical properties of the compared devices differ slightly. However, most results indicate that the Zirkonzahn devices performed in a slight better way than the predicates. These differences are considered non-significant. All devices meet the requirements of the standards.

Furthermore, Zirkonzahn indicates a shelf-life for its new devices while the predicate does not. Indicating a shelf life for those devices is customary as polymers are subject to decomposition over time. Thus, it does not represent a significant difference.

CONCLUSION

Based on the comparison made, it can be concluded that the new devices of Zirkonzahn and the IDODENTINE devices of Union Dental S. A. are substantially equivalent. There are not arising any new questions of safety and effectiveness form the comparison above.