September 5, 2023

Zirkonzahn Srl
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K232691
Trade/Device Name: Polibond
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: Class II
Product Code: EBI, ELM
Dated: September 1, 2023
Received: September 1, 2023

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 (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,

Michael E. Adjodha -S

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)*
K232691

Device Name
Polibond

Indications for Use *(Describe)*
Polibond is used to fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases.

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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K232691

510(k) Summary
Zirkonzahn GmbH / Srl
Polibond
8/24/2023

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Zirkonzahn GmbH / Srl An der Ahr 7 39030 Gais - Südtirol - Italy Telephone: +39 0474 066660	Consultant:	Aclivi, LLC 3250 Brackley Drive Ann Arbor, Michigan 48105 Telephone: +1 810 360-9773
Official Contact:	Sorana Siclovan - Project Management		Chris Brown - Manager
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Polibond
Device:	Resin, denture, relining, repairing, rebasing
Regulation Number:	21 CFR 872.3760
Regulation Name:	Denture relining, repairing, or rebasing resin
Device Class:	Class II
Product Code:	EBI
Review Panel:	Dental
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The Subject device in this submission is substantially equivalent in indications, use and design principles to the following Predicate device.

510(k)	Predicate Device Name	Company Name
K191926	VITA VIONIC Bond®	VITA Zanhnfabrik H. Rauter GmbH Co.

INDICATIONS FOR USE

Polibond is used to fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases.

DEVICE DESCRIPTION

The Subject device is a single-component self-cure bonding agent intended for use with milled PMMA denture base resins and milled PMMA denture teeth.

The Subject device is used by a dental professional (dentist or dental technician) in the fabrication or repair of removable dentures. Dentures fabricated using the Subject device are one-time use, prescription-only devices.

Polibond is intended for bonding Zirkonzahn PMMA materials such as Abro® Basic Mono, Abro® Basic Multistratum® and Denture Gingiva Basic Mono resins in the manufacturing of dental prostheses. Abro® Basic Mono and Abro® Basic Multistratum® are dentin colored and used for milling denture teeth. Denture Gingiva Basic Mono is a material used for milling denture bases.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is highly similar to the Predicate device with respect to Indications for Use and technological principles. The comparison tables below compare the Indications for Use and Technological Characteristics of the Subject, Predicate and Reference devices.

Indications For Use

Device	Indications for Use Statement
Subject Device Polibond Zirkonzahn GmbH / Srl	*Polibond is used to fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases.*
Predicate Device VITA VIONIC Bond® (K191926) VITA Zanhnfabrik H. Rauter GmbH Co.	*VITA VIONIC® Bond is used to fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases.*

The Subject and Predicate Indications for Use Statement (IFUS) are highly similar, only differing in the specific device names. The slight differences in the wording of the device names within Indications for Use Statements does not change the intended use of the Subject and Predicate devices to fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases.

Technological Characteristics

Parameter	**Subject Device** Polibond Zirkonzahn GmbH / Srl	**Predicate Device** VITA VIONIC Bond® (K191926) VITA Zanhnfabrik H. Rauter GmbH Co.	Comparison
Reason for Predicate/Reference	n/a	IFUS, Technological Characteristics,	n/a
Product Code	EBI	EBI	***Same***
Device	Resin, denture, relining, repairing, rebasing	Resin, denture, relining, repairing, rebasing	***Same***
Regulation	21 CFR 872.3760	21 CFR 872.3760	***Same***
Regulation Name	Denture relining, repairing, or rebasing resin	Denture relining, repairing, or rebasing resin	***Same***
Classification	Class II	Class II	***Same***
Intended Use	Fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases.	Fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases.	***Same***
Technology	Self-cure bonding agent for acrylic resin	Self-cure bonding agent for acrylic resin	***Same***
Biocompatible	Yes	Yes	***Same***
OTC or Rx	Rx	Rx	***Same***
Sterile	Non-sterile	Non-sterile	***Same***
How Supplied	Single bottle - Liquid	Two bottles – Liquid and Liquid	Similar*
Principle of Operation	Self-curing bonding agent when the liquid is applied to acrylic resin. (Self-curing)	Cured by chemical polymerization reaction starting with mixing the liquid and liquid component then applied to acrylic resin. (Self-curing)	Similar
Performance Testing	ISO 20795-1	ISO 20795-1	***Same***
Biocompatibility Testing	ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10	***Same***

*See discussion below

Product Code/Device/Regulation/Regulation Name/Classification/Intended Use/Technology/Biocompatible/ Rx/Sterility - The Subject and Predicate devices are the same.

How Supplied - The Subject and Predicate devices are similar as they are both liquids supplied in bottles. The Subject device is delivered in a single bottle, the Predicate device is two liquids supplied in separate bottles. The Subject device does not require mixing of liquids to accomplish the self-curing bonding process. The Predicate device requires mixing of two different liquids to create a compound that will result in a self-curing bonding agent. The number of bottles and need to mix does not change the intended use of the device to Fix custom-fit prosthetic teeth in appropriately milled cavities of prosthetic bases. The Subject device has demonstrated suitability for intended use through material non-clinical performance testing.

Principle of Operation - The Subject and Predicate devices are the same in that they are both self-curing agents when applied to acrylic resin. However, the Subject device creates a self-cure chemical bond with a single liquid applied between the custom fit prosthetic teeth and milled prosthetic base. The Predicate device requires mixing of two different liquids to create a compound that results in a self-curing bonding agent. The number of liquids and a requirement to mix liquids prior to application does not change the intended use of the devices. Differences in usage technique are mitigated through performance testing. The Subject device has demonstrated suitability for intended use through material non-clinical performance testing including comparative testing with the Predicate device.

Performance Testing – The Subject and Predicate devices were tested by their respective sponsors to the same ISO 20795-1 material property standard, meeting the relevant requirements of the standard which could be applied to a liquid such as the Subject device. Additionally, comparative tensile strength testing was performed with the Subject and Predicate devices and demonstrated similar performance.

Biocompatibility - The Subject and Predicate devices were tested to the same biological testing endpoints.

Overall, the Technological Characteristics of the Subject and Predicate devices are the Same or Similar. Technological differences between the Subject and Predicate devices have been evaluated through non-clinical performance testing. The results of the tests performed show that Subject device meets the requirements mentioned in the applicable standards and confirm that the Subject device performs similarly to the Predicate device based on the requirements of the standards.

CLINICAL AND ANIMAL TESTING

No clinical or animal testing data is included in this submission.

NON-CLINICAL PERFORMANCE TESTING

Physical property testing was performed on the Subject device to ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*. Results demonstrated the Subject device meets the property requirements of the referenced standards for the endpoints which could be applied to self-curing bonding agents for denture base polymers such as the Subject device. Comparative tensile strength testing was performed with the Subject and Predicate devices and demonstrated similar performance between the Subject and Predicate devices. Shelf-life testing was performed to support the shelf-life stated in device labeling.

A biological evaluation was performed on the Subject device. An abbreviated chemical characterization was performed along with a Toxicological Risk Assessment. Biocompatibility testing was performed on the Subject device according to ISO 10993-1:2018 according to the standards listed in the Technological Characteristics comparison table above.

An MRI safety assessment was performed on the Subject device to support MR Safety labeling as required by the FDA guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*".

Non-clinical performance testing of the Subject device met the acceptance criteria for each validation and test described above. This non-clinical performance testing demonstrates that the Subject device is suitable for intended use.

CONCLUSION

Overall, the Indications for Use statements for the Subject and Predicate devices are highly similar differing only in device name. Overall, the Technological Characteristics of the Subject device are the same or similar to the Predicate device with any differences mitigated through non-clinical performance testing.

Overall, these similarities between the Subject and Predicate devices support a determination of substantial equivalence.