June 28, 2018

Zirkonzahn GmbH
Sandra Leitner
Regulatory Affairs Responsible
Gewerbegebiet - Zona Industriale an der Ahr 7
Gais, 39030
ITALY

Re: K180562

Trade/Device Name: TEMP BASIC, TEMP PREMIUM, TEMP PREMIUM FLEXIBLE,
MULTISTRATUM FLEXIBLE, THERAPON, TRY-IN, BURNOUT, TRY-IN &
BURNOUT

Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: Class II
Product Code: EBG, POW
Dated: March 30, 2018
Received: April 3, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K180562

Device Name
TEMP BASIC, TEMP PREMIUM, TEMP PREMIUM FLEXIBLE, MULTISTRATUM FLEXIBLE, THERAPON, TRY-IN, BURNOUT, TRY-IN & BURNOUT

Indications for Use (Describe)
The resin discs TEMP PREMIUM, TEMP PREMIUM FLEXIBLE, MULTISTRATUM FLEXIBLE and THERAPON are polymethylmethacrylate and polycarbonate discs indicated to manufacture temporary anterior and posterior crowns and bridges, with up to two adjacent pontics, that can be kept in the mouth for up to 12 months. TEMP BASIC are PMMA discs intended for the fabrication of temporary anterior crowns and bridges, with up to one adjacent pontic, with a maximum recommended usage time of 12 months. TRY-IN, BURNOUT and TRY-IN & BURNOUT are PMMA discs intended for the fabrication of temporary crowns and bridges that can be kept in the mouth for up to 24 hours as for TRY-IN, and up to 60 minutes as for BURNOUT and TRY-IN &BURNOUT.

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
K180562

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E-mail: info@zirkonzahn.com

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E-mail: sandra.leitner@zirkonzahn.com

Date Summary Prepared: June 28, 2018

DEVICE IDENTIFICATION
Trade/Proprietary Name: TEMP BASIC, TEMP PREMIUM, TEMP PREMIUM FLEXIBLE, MULTISTRATUM FLEXIBLE, THERAPON, TRY-IN, BURNOUT, TRY-IN & BURNOUT
Generic/ Common Name: Dental polymer blanks (discs)
Classification name: 21 CFR 872.3770, CROWN AND BRIDGE, TEMPORARY, RESIN,
Class II
Product Code: EBG
Secondary Product Code: POW
Panel: Dental
**LEGALLY MARKETED PREDICATE AND REFERENCE DEVICES**

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Company</th>
<th>510(k) Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predicate Device</td>
<td>IDODENTINE</td>
<td>K150432</td>
</tr>
<tr>
<td>Reference Device</td>
<td>Polycarb</td>
<td>K022030</td>
</tr>
</tbody>
</table>

**INDICATIONS FOR USE:** The resin discs TEMP PREMIUM, TEMP PREMIUM FLEXIBLE, MULTISTRATUM FLEXIBLE and THERAPON are polymethylmethacrylate and polycarbonate discs indicated to manufacture temporary anterior and posterior crowns and bridges, with up to two adjacent pontics, that can be kept in the mouth for up to 12 months.

TEMP BASIC are PMMA discs intended for the fabrication of temporary anterior crowns and bridges, with up to one adjacent pontic, with a maximum recommended usage time of 12 months.

TRY-IN, BURNOUT and TRY-IN & BURNOUT are PMMA discs intended for the fabrication of temporary crowns and bridges that can be kept in the mouth for up to 24 hours as for TRY-IN, and up to 60 minutes as for BURNOUT and TRY-IN & BURNOUT.

**DEVICE DESCRIPTION**

**Intended use:** polymer blanks used in dental CAD/CAM milling systems by professional dental technicians to manufacture dental crowns and bridges

The subject devices are composed of polymethylmethacrylate (PMMA) or polycarbonates (PC) and pigments. They are available in different models that differ in basic material, form and color. The materials used for the submitted devices have a long history of safe use for same or equivalent indications.

The blanks are available in different forms (the diameter of the block can be 95 mm or 98 mm, with step or without step) and heights (from 8 to 30mm) for different milling systems.

The usage period of the subject devices is limited: TEMP BASIC, TEMP PREMIUM, TEMP PREMIUM FLEXIBLE, MULTISTRATUM FLEXIBLE and THERAPON discs can be kept in the oral cavity for up to 12 months; TRY-IN can be kept in the oral cavity for up to 24 hours, while BURNOUT and TRY-IN & BURNOUT devices can remain in the mouth for a maximum of 60 minutes.
DISCUSSION OF NON CLINICAL TESTS
The subject devices were tested according to ISO 10477:2004 to determine their flexural strength, water absorption and water solubility. All tested samples correspond with the requirements of the standard.

In consideration of the International Standard ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing, the subject devices were tested to evaluate: In-vitro cytotoxicity, Skin sensitization, Irritation, Mutagenicity. Biocompatibility testing demonstrated that no issue of biocompatibility arises.

The results of nonclinical tests demonstrate that the devices are equivalent to the predicate devices.

SUBSTANTIAL EQUIVALENCE DISCUSSION
The table below provides a more detailed comparison of the submitted devices and the predicate devices.

Both, the submitted devices and the predicates are made of polymers that have a well-documented history for use in medical device applications and have been in use for many years.

The submitted devices and the predicates have similar indications for use as well as comparable technical, physical, chemical and biological properties and characteristics.
<table>
<thead>
<tr>
<th>Company</th>
<th>ZIRKONZAHN GMBH</th>
<th>UNION DENTAL S.A.</th>
<th>INOVATIV, LLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation number</td>
<td>872.3770</td>
<td>872.3770</td>
<td>872.3770</td>
</tr>
<tr>
<td>Product Code</td>
<td>EBG</td>
<td>EBG</td>
<td>EBG</td>
</tr>
<tr>
<td>Classification name</td>
<td>Temporary crown and bridge resin.</td>
<td>Temporary crown and bridge resin.</td>
<td>Temporary crown and bridge resin.</td>
</tr>
<tr>
<td>Indications for use</td>
<td>The resin discs TEMP PREMIUM, TEMP PREMIUM FLEXIBLE, MULTISTRATUM FLEXIBLE and THERAPON are polymethylmethacrylate and polycarbonate discs indicated to manufacture temporary anterior and posterior crowns and bridges, with up to two adjacent pontics, that can be kept in the mouth for up to 12 months. TEMP BASIC are PMMA discs intended for the fabrication of temporary anterior crowns and bridges, with up to one adjacent pontic, with a maximum recommended usage time of 12 months. TRY-IN, BURNOUT and TRY-IN &amp; BURNOUT are PMMA discs intended for the fabrication of temporary anterior crowns and bridges, with up to one adjacent pontic, with a maximum recommended usage time of 12 months.</td>
<td>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)</td>
<td>The Polycarb is intended for the fabrication of temporary dental prostheses like partial denture clasps, temporary crowns, and bridges using the Inovativ, LLC Polycarb resin.</td>
</tr>
</tbody>
</table>

Similar. The Zirkonzahn devices are more limited in their indications for use. No new questions of safety and effectiveness are arising as the indications are not expanded, but more restricted.
fabrication of temporary crowns and bridges that can be kept in the mouth for up to 24 hours as for TRY-IN, and up to 60 minutes as for BURNOUT and TRY-IN & BURNOUT.

### Components
- **PMMA or PC based resins with approx. 1% pigments**
- **PMMA >99% wt. Pigments <1% wt.**
- **PC based resin**

### Intended user
- **Professional dental technicians**

### Physical Properties
- **According to ISO 10477:2004**
- **N/A**

<table>
<thead>
<tr>
<th>Flexural Strength</th>
<th>TEMP BASIC: 64 MPa</th>
<th>TEMP PREMIUM: 106 MPa</th>
<th>TEMP PREMIUM FLEXIBLE: 110 MPa</th>
<th>TEMP PREMIUM FLEXIBLE: 120 MPa</th>
<th>THERAPON: 115 MPa</th>
<th>TRY-IN: 65.32 MPa</th>
<th>BURNOUT: 53.66 MPa</th>
<th>TRY-IN &amp; BURNOUT: 57.34 MPa</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDODENTINE MULTILAYER: 83 MPa</td>
<td>IDODENTINE TRANSPA: 94 MPa</td>
<td>N/A</td>
<td></td>
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</tr>
</tbody>
</table>

**Similar**
- The Temp Basic, Try-In, Burnout and Try-In & Burnout have lower values. These differences are not significant, due to their limited usage.

<table>
<thead>
<tr>
<th>Water absorption</th>
<th>TEMP BASIC: 20.46 µg/mm³</th>
<th>TEMP PREMIUM: 19.36 µg/mm³</th>
<th>TEMP PREMIUM FLEXIBLE: 3.97 µg/mm³</th>
<th>MULTISTRATUM FLEXIBLE: 2.90 µg/mm³</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDODENTINE MULTILAYER: 22.3 µg/mm³</td>
<td>IDODENTINE TRASPA: 25.8 µg/mm³</td>
<td>N/A</td>
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</tr>
</tbody>
</table>

**Similar**
<table>
<thead>
<tr>
<th>THERAPON: 14.1 µg/mm³</th>
<th>TRY-IN: 20.47 µg/mm³</th>
<th>BURNOUT: 20.10 µg/mm³</th>
<th>TRY-IN &amp; BURNOUT: 19.68 µg/mm³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water solubility</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>TEMP BASIC: 0 µg/mm³</td>
<td></td>
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<tr>
<td>TEMP PREMIUM: &lt;1 µg/mm³</td>
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<tr>
<td>TEMP PREMIUM FLEXIBLE: 1.98 µg/mm³</td>
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<tr>
<td>MULTISTRATUM FLEXIBLE: 0 µg/mm³</td>
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</tr>
<tr>
<td>THERAPON: 0 µg/mm³</td>
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<td></td>
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</tr>
<tr>
<td>TRY-IN: 0.69 µg/mm³</td>
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<tr>
<td>BURNOUT: 1.00 µg/mm³</td>
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<tr>
<td>TRY-IN &amp; BURNOUT: 1.51 µg/mm³</td>
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<tr>
<td>IDODENTINE MULTILAYER: 0.7 µg/mm³</td>
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<tr>
<td>IDODENTINE TRANSPARENT: 0.9 µg/mm³</td>
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**CONCLUSION**

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