Dear Sasha Der Avanessian:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Mary S. Runner -S3
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)
K180578

Device Name
Harvest Dental Polymer Blocks

Indications for Use (Describe)

Indications for Use:
For the fabrication of crowns, bridges and structures for implant supported provisional removable denture and appliance prosthetics.
- Provisional anterior and posterior crowns & bridges
- Implant and abutment supported prosthetics.
- Partial, complete and hybrid denture prosthetics (base and teeth) - Removable appliances (splint)

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
This Summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510K Submitter
Harvest Dental Products, LLC
905 Columbia St, Brea, CA 92821
Tel: 714-674-7400
hello@harvestdental.com

Contact person:
Sasha Der Avanessian
President & CEO
Tel: 714-674-7400
sasha@harvestdental.com

Date Summary was prepared
12/11/18

Trade Name of device:
Harvest Dental Polymer Blocks

Common name:
Crown & Bridge, Temporary, Resin

Classification name:
TEMPORARY CROWN AND BRIDGE RESIN. (21 CFR 872.3770 - Product code EBG)

Classification Product Code
EBG

Panel
Dental

Classification
Class II

Predicate Device
K150432
Union Dental S.A
Idodentine (Dental Polymer Blank)
Indications for Use:

For the fabrication of crowns, bridges and structures for implant supported provisional removable denture and appliance prosthetics.
- Provisional anterior and posterior crowns & bridges
- Implant and abutment supported prosthetics.
- Partial, complete and hybrid denture prosthetics (base and teeth)
- Removable appliances (splint)

Device Description:

Harvest Dental Polymer Blocks are industrially polymerized, pre-colored or clear dental milling discs and blocks designed for milled fabrication of temporary anterior and posterior crowns and bridges (tooth-colored variants) or bite splints and dental CAD/CAM systems.

Technological characteristics

The technologic characteristics are highly similar as demonstrated in performance testing and in chemical composition; both devices are composed primarily of polymethylmethacrylate, while the amount and percentage of color oxides in the submission device varies from the predicate.

Comparison of Required Technology Characteristics

The following table shows a summary of the technological characteristics of DD medical polymers compared to the predicate device.
### Comparision of Required Technology Characteristics

<table>
<thead>
<tr>
<th>Feature</th>
<th>Submission device</th>
<th>Predicate device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade name</td>
<td>Harvest Dental Polymer Blank</td>
<td>Idodentine Disc</td>
</tr>
<tr>
<td>510 (K)</td>
<td>K180578</td>
<td>K150432</td>
</tr>
<tr>
<td>Product code</td>
<td>EBG</td>
<td>EBG</td>
</tr>
<tr>
<td>Regulatory Class</td>
<td>CLASS II</td>
<td>Class II</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Harvest Dental</td>
<td>Union Dental S.A</td>
</tr>
</tbody>
</table>

**Indications for use**

For the fabrication of crowns, bridges and structures for implant supported provisional removable denture and appliance prosthetics.
- Provisional anterior and posterior crowns & bridges.
- Implant and abutment supported prosthetics.
- Partial, complete and hybrid denture prosthetics (base and teeth).
- Removable appliances (splint)

Acrylic polymer blank particularly suitable for making removable or temporary dental structures such as crowns and bridges using milling technology using CAD/CAM.

Indications
- Temporary anterior and posterior crowns
- Temporary anterior and posterior bridges with up to two adjacent pontics
- Removable structures for dentures (denture bases)
- Removable structures for therapeutic restorations (bite splints or occlusal splints)

**Technology**

Blank for dental CAD/CAM

**Shape**

Disc or Block

**Shade**

VITA-shades, clear, pink

### Comparision of Required Technology Characteristics

<table>
<thead>
<tr>
<th>Raw Material</th>
<th>PMMA</th>
<th>PMMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Compositions [Units]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material Base</td>
<td>Polymethyl methacrylate</td>
<td>Polymethyl methacrylate</td>
</tr>
<tr>
<td>Coloring oxides</td>
<td>&lt; 1,1%</td>
<td>Not specified</td>
</tr>
</tbody>
</table>

### Physical Characteristics [Units]

<table>
<thead>
<tr>
<th>Performance Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 10477</td>
</tr>
<tr>
<td>ISO 20795</td>
</tr>
<tr>
<td>Tested according to DIN EM ISO 20795-1 and ISO 10477</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Biocompatibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 10993</td>
</tr>
<tr>
<td>No cytotoxic</td>
</tr>
<tr>
<td>E.N ISO 10933-1, -5,</td>
</tr>
</tbody>
</table>
Preclinical testing and standards
Clinical and Non clinical performance

The biocompatibility test for “Harvest Dental Polymer Blocks” was made in the laboratory and all the results was:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Conclusion</th>
<th>Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 10993-10, 2010.</td>
<td>In the test conditions, the test substance Harvest Dental Polymer Blocks was classified as no sensitizing.</td>
<td>Report Number: RL15885/2018LLNA-B  Study Number: 15885/2018LLNA</td>
</tr>
<tr>
<td>ISO 10993-10, annex B3 2010.</td>
<td>Under the study conditions, the test substance Harvest Dental Polymer Blocks was classified as non-irritant to oral mucose of hamsters, according to ISO10993: 10, 2010.</td>
<td>Report Number: RL15886/2018IMO-B  Study Number: 15886/2018IMO</td>
</tr>
<tr>
<td>ISO 10993-5, 2009 annex C</td>
<td>Under the conditions of this study, the test substance Harvest Dental Polymer Blocks did not promote reduction of cell viability higher than 30%. Therefore the test substance Harvest Dental Polymer Blocks was not cytotoxic in this assay.</td>
<td>Report Number: RL16016/2018CT-B  Study Number: 16016/2018CT</td>
</tr>
</tbody>
</table>

This PMMA has been tested for biocompatibility and physical properties. This PMMA used has been rated as biocompatible and non-toxic and this PMMA material also met the applicable requirements of ISO 10447(crown & bridges material), and ISO 22112(polymer teeth) standards. The subject device has passed testing according to ISO 10477/2004: DENTISTRY – POLYMERBASED CROWN AND BRIDGE MATERIALS. This international standard specifies the classification, requirements and test methods for the polymer-based crown and bridge materials. The subject device also has passed testing according to ISO 10993-5 and has been rated as Non cytotoxic.

Standards:
ISO 10477:2004 – Dentistry Polymer-Based crown and Bridge Materials  
ISO 22112:2005 - Polymer teeth  
ADA – 53 – Polymer-Based crown and Bridge Resin
<table>
<thead>
<tr>
<th>Requirement</th>
<th>Required Value (ISO 20795-1)</th>
<th>Required Value (ISO 10477)</th>
<th>Value Subm. Device</th>
<th>Value Predicate Device</th>
<th>Passed/Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexural strength</td>
<td>≥ 65 [MPa]</td>
<td>≥ 50 [MPa]</td>
<td>&gt; 90 Mpa</td>
<td>90 [MPa]</td>
<td>Passed</td>
</tr>
<tr>
<td>Water absorption</td>
<td>≤ 32 [µg/mm³]</td>
<td>≤ 40 [µg/mm³]</td>
<td>0.024 mg/mm³</td>
<td>23 [µg/mm³]</td>
<td>Passed</td>
</tr>
<tr>
<td>Water solubility</td>
<td>≤ 1.6 [µg/mm³]</td>
<td>≤ 7.5 [µg/mm³]</td>
<td>0.0000 mg/mm³</td>
<td>0.0 [µg/mm³]</td>
<td>Passed</td>
</tr>
<tr>
<td>Residual monomer content [%]</td>
<td>≤ 2.2 %</td>
<td>-</td>
<td>&lt; 1,1%</td>
<td>1.4 %</td>
<td>Passed</td>
</tr>
</tbody>
</table>
Substantial Equivalence:

The differences in indications for use are limited to the following wording differences as follows:

<table>
<thead>
<tr>
<th>Submission Device</th>
<th>Predicate device</th>
<th>Differences</th>
<th>Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fabrication of crowns, bridges</td>
<td>Same</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td>Structures for implant supported provisional removable denture and appliance prosthetics.</td>
<td>Temporary</td>
<td>The use of the word provisional verses Temporary</td>
<td>Note 1</td>
</tr>
<tr>
<td>Provisional anterior and posterior crowns &amp; bridges.</td>
<td>Same</td>
<td>with up to two adjacent pontics</td>
<td>Note 2</td>
</tr>
<tr>
<td>Implant and abutment supported prosthetics.</td>
<td>Same</td>
<td>bite splints or occlusal splints</td>
<td>Note 3</td>
</tr>
<tr>
<td>- Partial, complete and hybrid denture prosthetics (base and teeth).</td>
<td>Same</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum recommended usage period: 12 months</td>
<td>Submission doesn’t use these words</td>
<td>Note 1</td>
<td></td>
</tr>
<tr>
<td>Acrylic polymer blank</td>
<td>Submission doesn’t use these words</td>
<td>Note 4</td>
<td></td>
</tr>
<tr>
<td>using milling technology using CAD/CAM.</td>
<td>Submission doesn’t use these words</td>
<td>Note 5</td>
<td></td>
</tr>
</tbody>
</table>

Note 1
These two words can often be used interchangeably, however not necessarily meaning the same thing in true context. For example:-
The Predicate device uses “Temporary” meaning the device is expected to come to an end, in their case at 12 months.
The Submission device uses the word “Provisional” meaning that it will come to an end but doesn’t mean that it has finished it’s useful life.

The reason we chose the word “Provisional” is to establish that our device can actually last a lot longer than 12 months as indicated in our “Shelf life report” and our description of device, which shows the device can actually remain in place for 5 years. This is supported by the test data submitted in this review. Again this use of the word has no adverse impact on the safety or effective performance of the submitted device.
Note 2
Pontics are used to replace missing teeth, however the primary causes of complications in implant dentistry are related to biomechanics. For example, early loading failures especially in soft bone, when forces are greater than usual and/or implant sizes are shorter than 10mm.

The number of pontics for a prosthesis is related to strength of the abutments and the number of pontics with implants is often increased compared to natural teeth which can cause a problem.

In fixed prosthesis design, three adjacent pontics in the posterior regions of the mouth are contraindicated with natural. The adjacent abutments are subjected to considerable additional force when they must support three missing teeth, especially in the posterior regions of the mouth.

Also the occlusal force to the five posterior teeth cannot be supported by two implants. The posterior regions have greater bite forces than the anterior regions. This is because typically the teeth in the posterior have less bone density, which puts an increased load on the anterior teeth.

The additional forces distributed to the pontic abutments will cause them to flex under load. The greater the span the greater the flex on the pontic causing potential mechanical shear and tensile load failure on the abutments.

The chart below shows the additional flex placed on a pontic assuming a load of 25lbs and all other variables being equal.

<table>
<thead>
<tr>
<th># of Pontics</th>
<th>Flex</th>
<th>Accept/Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8 µ - 0.01 mm</td>
<td>Accept</td>
</tr>
<tr>
<td>2</td>
<td>64 µ - 0.08 mm</td>
<td>Accept</td>
</tr>
<tr>
<td>3</td>
<td>216 µ - 0.216 mm</td>
<td>Reject</td>
</tr>
</tbody>
</table>

Flex is not so much an issue on natural teeth as they have a small degree of natural flex, apically and laterally in the area of the root. However an implant is more ridged due to its increased modulus of elasticity (Doesn’t flex as much as a natural tooth).

Further more angled forces increase the stress and strain on an implant restoration especially in the maxillary anterior teeth. This can lead to porcelain fractures, abutment screws working loose and uncrementing of the restoration causing even more stress on the restoration. More stress forces can cause the pontic to cantilever, creating an increased risk of crestal bone loss, failure of the implant or fracture of an abutment screw or implant body, especially in the posterior region due to greater bite force.
Pontics should be limited to 2 in proportion to the size of the premolars, typically between 13.5mm – 16mm. There are instances when a molar is one of the missing teeth to be replaced, which is between existing teeth creating a space between 10-15mm. In the instance when the space is greater than 15mm it is better for the doctor to use two pontics to replace the molar. Therefore when a 2nd premolar and 1st molar are missing it would require the doctor to plan the replacement of 3 teeth rather than two as the span is related to the number of roots in the mandible and buccal roots in the maxilla.

By using 3 pontics or more in either a fixed prosthesis or implant restoration is contraindicative and a skilled restoration specialized would always design a restoration using a maximum of 2 pontics where possible or use more implants.

Therefore to either state or not state 2 pontic on the Substantial Equivalence indications has no impact on safety or effectiveness of the submitted device, as this is a decision of the specialist doctor when designing the Provisional anterior and posterior crowns & bridges.

Note 3
We have deliberately left out the need to use the Polymer block for the use of bite splints or occlusal splints, even though this material can actually be used for both we will market a separate material to cover this need. This has no impact on the submitted device for safety or effectiveness.

Note 4
The use of the word “Acrylic Polymer Blank” is not required as this is already a given. This has no impact on the submitted device for safety or effectiveness.

Note 5
The use of the words “using milling technology using CAD/CAM is not required as this is also a given. This has no impact on the submitted device for safety or effectiveness.

Conclusion

Information provided in this 510(k) submission shows that the product is substantially equivalent to the Harvest Dental Polymer Block as predicate device Idodentine Blank.

Based on comparison of technology, including composition and performance testing, biocompatibility testing, and highly similar indications for use, Harvest Dental Polymer Blocks are equivalent to Idodentine (K150432).