December 21, 2022

Mgnewton LTD.
℅ Priscilla Chung
LK Consulting Group USA, Inc.
1150 Roosevelt, Suite 200
Irvine, California 92620

Re: K202965
Trade/Device Name: CURA-Temp
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: December 2, 2022
Received: December 5, 2022

Dear Priscilla Chung:

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K202965

Device Name
CURA-Temp

Indications for Use *(Describe)*

Fabrication of temporary crowns, bridges, inlays, onlays and veneers. Fabrication of long-lasting temporary restorations. Lining material for prefabricated temporary crowns made of composite and metal.

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.***

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# 510(k) Summary
(K202965)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: Oct 6, 2021

**1. 510K Applicant / Submitter:**

MGNEWTON LTD.
472, Hanjanggun-ro, Jain-myeon, Gyeongsan-si, Gyeongsangbuk-do, Republic of Korea
Tel: +82-53-214-6287
Fax: +82-70-7469-2074

**2. Submission Contact Person**

LK Consulting Group USA, Inc.
1150 ROOSEVELT, SUITE 200 Irvine , CA 92620
Priscilla Chung
Phone: 714 2025789 Ext
Email: Juhee.C@Lkconsultinggroup.com

**3. Subject Device**

-. Trade Name : CURA-Temp
-. Classification Name : Crown and Bridge, Temporary, Resin
-. Regulation Number : 21 CFR 872.3770
-. Regulation Name : Temporary crown and bridge resin
-. Regulatory Class : II
-. Product Code : EBG

**4. Primary Predicate Device**

-. Trade Name : TempXN28 (currently marketed as Protemp Plus)
-. 510(k) Number : K073296
-. Regulation Number : 21 CFR 872.3770
-. Regulation Name : Temporary crown and bridge resin
-. Regulatory Class : II
-. Product Code : EBG

**5. Description:**

This product is ISO10477 Type 2 & Class 2, a light cured resin that forms the shape of a resin to make a temporary crown to protect the tooth for crown treatment for a certain period until the prosthesis is made. It is packaged in an impermeable syringe which is polymerized by light-cured energy and composed of base and photocatalytic agent.

## 6. Indications for Use

Fabrication of temporary crowns, bridges, inlays, onlays and veneers. Fabrication of long-lasting temporary restorations. Lining material for prefabricated temporary crowns made of composite and metal.

## 7. Substantial Equivalence Discussion:

The CURA-Temp is substantially equivalent to TempXN28 (K073296). The following comparison table is presented to demonstrate substantial equivalence.

| Item | | Our Device | Equivalence Device | Degree |
|---|---|---|---|---|
| **Manufacturer** | | MGNEWTON Ltd. | 3M ESPE AG | - |
| **Product Name** | | CURA-Temp | TempXN28 (currently marketed as Protemp Plus) | - |
| **510(k) Number** | | Pending | K073296 | - |
| **Technical Equivalence** | Appearance |  |  | - |
| | Design type | Syringe | Syringe | Identical |
| | Depth of cure | 99 % | the bottom surface shall be not less than 70% of that of the top surface | **Different #1** |
| | Flexural Strength | Avg. 83.5 MPa | ≥ 50 MPa | **Different #2** |
| | Water Sorption | Avg. 19.4 $\mu g/mm^3$ | ≤ 40 $\mu g/mm^3$ | **Different #3** |
| | Solubility | Avg. 2.72 $\mu g/mm^3$ | ≤ 7.5 $\mu g/mm^3$ | **Different #4** |
| | Color Stability | no a slight change in colour | shall show no more than a slight change in colour | Identical |
| | Shade consistency | no a slight change in colour | shall show no more than a slight difference with the colour indicated | Identical |
| | Surface finish | A glossy surface | shall have a glossy surface | Identical |
| | Accessory | -. CURA-Temp Polisher<br>-. CURA-Temp Adhesive<br>-. CURA-Temp Tray<br>-. Bur | -. Polisher<br>-. Adhesive<br>-. Tray<br>-. Bur | Identical |
| | Condition of use | Used as a temporary crown for a teeth that needs restoring. | Used as a temporary crown for a teeth that needs restoring. | Identical |

<table>
<tr><td></td><td>Principles of operation</td><td>Raw materials are photopolymerized and applied to teeth needed to be repaired for temporary restoration.</td><td>Raw materials are photopolymerized and applied to teeth needed to be repaired for temporary restoration.</td><td>Identical</td></tr>
<tr><td rowspan="5">Clinical Equivalence</td><td>Indications for Use</td><td>Fabrication of temporary crowns, bridges, inlays, onlays and veneers. Fabrication of long-lasting temporary restorations. Lining material for prefabricated temporary crowns made of composite and metal.</td><td>Fabrication of temporary crowns, bridges, inlays, onlays and veneers. Fabrication of long-lasting temporary restorations. Lining material for prefabricated temporary crowns made of composite and metal.</td><td>Identical</td></tr>
<tr><td>Intended User</td><td>Dentist</td><td>Dentist</td><td>Identical</td></tr>
<tr><td>Application Area</td><td>Gum</td><td>Gum</td><td>Identical</td></tr>
<tr><td>Target Population</td><td>All age</td><td>All age</td><td>Identical</td></tr>
<tr><td>Period of use</td><td>A month</td><td>A month</td><td>Identical</td></tr>
<tr><td rowspan="2">Biological Equivalence</td><td>Raw Material</td><td><table><tr><th>No.</th><th>Materials</th></tr><tr><td>1</td><td>Bisphenol A glycidyl Methacrylate</td></tr><tr><td>2</td><td>Urethane Dimethacrylate</td></tr><tr><td>3</td><td>Triethyleneglycoldimethacrylate</td></tr><tr><td>4</td><td>Glass</td></tr><tr><td>5</td><td>Silane, dichlorodimethyl-, reaction products with silica</td></tr><tr><td>6</td><td>Camphorquinone</td></tr><tr><td>7</td><td>Ethyl 4-dimethylaminobenzoate</td></tr><tr><td>8</td><td>Titanium(IV) oxide</td></tr><tr><td>9</td><td>Yellow ferric oxide</td></tr><tr><td>10</td><td>Iron(III) oxide, Red</td></tr><tr><td>11</td><td>Iron(II, III) oxide, Black</td></tr></table></td><td>Bis-acrylic composite</td><td>Different #5</td></tr>
<tr><td>Bio-compatibility</td><td>Compliance with EN ISO 10993-1</td><td>Compliance with EN ISO 10993-1</td><td>Identical</td></tr>
</table>

※ Gap Analysis

1) #1 Difference (Depth of cure)

In terms of depth of cure, our product is 99% and the predicate device is 70% or more. But, the depth of cure of our product and the predicate device was tested in accordance with ISO 10477 and the criteria that the bottom surface shall be not less than 70% of that of the top surface was applied equally. Therefore, despite the difference in the depth of cure between our product and the predicate device, since both products were manufactured in compliance with ISO 10477, there are no difference in terms of clinical performance and safety.

2) #2 Difference (Flexural Strength)

In terms of flexural strength, our product is an average of 83.5 MPa and the predicate device is ≥ 50 MPa. But, the Flexural Strength of our product and the predicate device was tested in accordance with ISO 10477 and the criteria that ≥ 50 Mpa was applied equally. Therefore, despite the difference in the Flexural Strength between our product and the predicate device, since both products were manufactured in compliance with ISO 10477, there are no difference in terms of clinical performance and safety.

3) #3 Difference (Water Sorption)
In terms of water sorption, our product is an average of 19.4 ㎍/mm3 and the predicate device is ≤ 40 ㎍/mm3. But, the Water Sorption of our product and the predicate device was tested in accordance with ISO 10477 and the criteria that ≤ 40 ㎍/mm3 was applied equally. Therefore, despite the difference in the Water Sorption between our product and the predicate device, since both products were manufactured in compliance with ISO 10477, there are no difference in terms of clinical performance and safety.

4) #4 Difference (Solubility)
In terms of solubility, our product is an average of 2.72 ㎍/mm3 and the predicate device is ≤ 7.5 ㎍/mm3. But, the Solubility of our product and the predicate device was tested in accordance with ISO 10477 and the criteria that ≤ 7.5 ㎍/mm3 was applied equally. Therefore, despite the difference in the Solubility between our product and the predicate device, since both products were manufactured in compliance with ISO 10477, there are no difference in terms of clinical performance and safety.

5) #5 Difference (Raw Material)
In current clinical restorative treatment, many types of resin composites are available for the replacement of natural tooth tissues. The raw materials of our product and the similar product have a little difference in specific components and their composition. However, both products belong to the category of bis-acrylic composite. It would be impossible to find the details of raw materials of other company's product, as they are trade secrets but in general bis-acrylic composite includes both bisphenol a glycidyl methacrylate and urethane dimethacrylate of our product. The predicate device is a CE certified device and its safety has been proved. We conducted the biological safety test of our product to confirm its bio safety. We confirmed the technical and clinical equivalence. Despite the difference in biological equivalence, the bis-acrylic composite, which is dental resin, is biologically safe.

These composites are considered to be same. For this reason, although there is difference of raw materials between our product and similar product, it does not affect the clinical safety of our product.

**8. Performance Tests (Non-clinical)**

Non-clinical performance tests were performed according to the test standard (ISO 10477:2004).
The following tests for performance of the subject device have been conducted.

| Test Standard | Test Item |
|---|---|
| - | Appearance |
| - | Weight |
| - | Packaging |

| | |
|---|---|
| ISO 10477 | Flexural Strength |
| ISO 10477 | Water Sorption |
| ISO 10477 | Solubility |
| ISO 10477 | Shade consistency (Color) |
| ISO 10477 | Colour Stability |
| ISO 10477 | Sensitivity to Ambient Light |
| ISO 10477 | Dept of cure |
| ISO 10477 | Surface Finish |

The test results met all the requirements of ISO 10477 and based on that, we conclude that the subject device will perform as well as the predicate devices in the market.

## 9. Biocompatibility Test

The following tests for biocompatibility have been conducted on the subject device;

| **Test Standard** | **Test Item** |
|---|---|
| ISO 10993-5 | Cytotoxicity (Agar Diffusion) |
| ISO 10993-10 | Oral mucosa irritation |
| ISO 10993-10 | Skin Sensitization (LLNA) |
| ISO 10993-11 | Acute Systemic Toxicity (Oral) |

## 10. Conclusions:

Based on the information above, CURA-Temp has the same indications for use and the technological characteristics as the predicate device. Both the subject device and the predicate have shown similar performance results in these bench tests.
In conclusion, CURA-Temp is substantially equivalent to the predicate device as described herein.