



Food and Drug Administration  
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December 18, 2014

Liaoning Upcera Co., Ltd.  
C/O Mr. Charles Shen  
Regulatory Correspondent  
Manton Business and Technology Services  
853 Dorchester LN Unit-B  
New Milford, NJ 07646

Re: K141727

Trade/Device Name: Dental Lithium Disilicate Glass Ceramic Block (Up. Press  
Series and UP. CAD Series)

Regulation Number: 21 CFR 872.6660

Regulation Name: Porcelain powder for clinical use

Regulatory Class: II

Product Code: EIH

Dated: November 20, 2014

Received: November 25, 2015

Dear Mr. Shen:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Susan Runna DDS, MA". The signature is written in a cursive style. In the background, there is a faint, large watermark of the letters "FDA".

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Section 4: Indications for Use**

510(k) Number (if known): N/A K141727

Device Name: Dental Lithium Disilicate Glass Ceramic Block (Up. Press Series and Up. CAD Series)

Indications for Use:

Dental Lithium Disilicate Glass Ceramic Blocks (Up. Press Series and Up. CAD Series) are indicated for fabricating all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## Section 5: 510(k) Summary: K141727

### 5.1 Submitter & Foreign Manufacture Identification

Liaoning Upcera Co., Ltd  
No.122 Xianghuai Road, Economic Development Zone, Benxi, Liaoning, China  
Tel: (086) 24-45565006  
Submitter's FDA Registration Number: 3010582952  
www.upcera-dental.com

### 5.2 Contact Person

Charles Shen  
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853 Dorchester LN, Unit-B  
New Milford, NJ 08534  
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### 5.3 Date of Summary: December 15, 2014

### 5.4 Device Name:

<b>Proprietary Name:</b>	Dental Lithium Disilicate Glass Ceramic Block (Up. Press Series and Up. CAD Series)
<b>Common Name:</b>	Dental Glass Ceramics
<b>Classification Name:</b>	Porcelain Powder for Clinical Use
<b>Device Classification:</b>	II
<b>Regulation Number:</b>	21 CFR 872.6660
<b>Panel: General</b>	Dental
<b>Product Code:</b>	EIH

### 5.5 Predicate Device Information:

(1) K123952, "CEREC Blocs C In", manufactured by "Sirona Dental Systems GmbH"

### 5.6 Device description:

Dental Lithium Disilicate Glass Ceramic Block (Up. Press Series and Up. CAD Series) are derived from dental porcelain powder that has been processed into their final net shapes. These blanks are then being further fabricated (using hot press or CAD/CAM technologies) into all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns. The ceramics material is composed of SiO<sub>2</sub>, Li<sub>2</sub>O, K<sub>2</sub>O, P<sub>2</sub>O<sub>5</sub>, Al<sub>2</sub>O<sub>3</sub>, B<sub>2</sub>O<sub>3</sub>, and other oxides. It also contains inorganic pigments (Er<sub>2</sub>O<sub>3</sub>, V<sub>2</sub>O<sub>5</sub>,

and MnO<sub>2</sub>) to provide different shades on the product surface. The performance of this lithium silicate dental blank conforms to ISO 6872, *Dentistry: Ceramic Materials*

**5.7 Intended Use:**

Dental Lithium Disilicate Glass Ceramic Blocks (Up. Press Series and Up. CAD Series) are indicated for fabricating all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.

**5.8 Summary of Device Testing:**

Bench testing was performed per ISO 6872:2008 and internal procedures to ensure that the Dental Lithium Disilicate Glass Ceramic Block (Up. Press Series and Up. CAD Series) met its specifications. All tests were verified to meet acceptance criteria.

Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

**5.9 Comparison with Predicate Device:**

“Dental Lithium Disilicate Glass Ceramic Block (Up. Press Series and Up. CAD Series)” are compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

- (1) K123952, “CEREC Blocs C In”, manufactured by “Sirona Dental Systems GmbH”

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

**Table 5.1: Comparison of Intended Use, Design, Material, and Processing**

Description	Subject Device	Predicate Device (K123952)
Indication for Use	Dental Lithium Disilicate Glass Ceramic Blocks (Up. Press Series and Up. CAD Series) are indicated for fabricating all-ceramic restorations such as veneers, inlay/ onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.	CEREC blocs C In are indicated for the fabrication of veneers and of crowns in anterior teeth and in premolars that have not been endodontically treated, using the Sirona CAD/CAM system.
Materials	SiO <sub>2</sub> , Li <sub>2</sub> O, K <sub>2</sub> O, P <sub>2</sub> O <sub>5</sub> , Al <sub>2</sub> O <sub>3</sub> , B <sub>2</sub> O <sub>3</sub> , and other oxides	SiO <sub>2</sub> , K <sub>2</sub> O, Na <sub>2</sub> O, Al <sub>2</sub> O <sub>3</sub> , B <sub>2</sub> O <sub>3</sub> , and other oxides
Processing	Sintering at temperature 1450-1550 °C	Sintering at un-disclosed temperature
Processing at	Hot Press (Up. Press Series)	CAD/CAM

Dental lab	CAD/CAM (Up. CAD Series)	
Geometry	Blocks, disc, and rod	Blocks
Dimension	Various	Various
Single Use	Yes	Yes
Available Color	Various	Various
Sterile	Non-sterile	Non-sterile

Our device is very similar to the predicate device in terms of indications for use, design, material (same material vendor), and processing between our device and the predicate devices. There are three minor differences that are worth discussing:

- (1) Compared with predicate device, the subject device has a slight different phrasing of potential dental applications in the Indications for Use Statement. This difference in wording is minor, and all applications for the subject device is compliant to the recommended clinical indications in Table 1 of ISO 6872: 2008
- (2) The subject and predicate device have slight difference in composition. But they both have silicate and alkaline metal oxide as the major component. For example, the subject device has SiO<sub>2</sub>, Li<sub>2</sub>O, K<sub>2</sub>O, and the predicate device has SiO<sub>2</sub>, Na<sub>2</sub>O, K<sub>2</sub>O. Note that lithium and sodium belong to the same group of alkaline metals and display very similar physical and chemical properties.
- (3) The predicate device will be CAD/CAM processed at dental labs, and the subject device can be either CAD/CAM processed or hot pressed. It has long been proven in the industry that CAD/CAM processing and hot pressing are similar in terms of product final physical and chemical properties. This is also demonstrated in our performance testing that products from the Up. Press and Up. CAD series are almost equivalent in performance (see Table 12.2 below).

The following table shows similarities and differences of the key performance between our device and the predicate devices. Tests were conducted following applicable procedures outlined in the FDA recognized consensus standard of ISO 6872, and results met all relevant requirements in the test standards, and are comparable to the predicate device in performance.

The only minor difference is that subject device has higher flexural strength and potentially wider dental applications compared with predicate device.

**Table 5.2: Comparison of Performance Testing**

Description	Subject Device: Up. Press Series and Up. CAD Series	Predicate Device (K123952)
Radioactivity (Bq•g <sup>-1</sup> )	Meet the requirements of ISO 6872:2008	Meet the requirements of ISO 6872:2008
Density (g/cm <sup>3</sup> )		
Flexural Strength (MPa)		
Coefficient of Thermal Expansion (K <sup>-1</sup> )		
Glass Transition Temperature (°C)		

The following table shows similarities and differences of the biocompatibility between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the FDA recognized consensus standard of ISO 10993, and results met all relevant requirements in the test standards, and are comparable to the predicate device.

**Table 5.3: Comparison of Biocompatibility Testing**

Description	Our Device	Predicate Device (K123952)
Cytotoxicity (ISO 10993-5:2009)	No cyteotoxicity effect	Biocompatible per ISO 10993-1.
Irritation Oral Mucosa Irritation (ISO 10993-10: 2010)	Not a primary oral mucosa irritant under the conditions of the study	
Sensitization (ISO 10993-10: 2010)	Not a sensitizer under the conditions of the study	
Subacute and Subchronic Toxicity (ISO 10993-11: 2006)	No subacute and subchronic toxic effects observed	
Genotoxicity (ISO 10993-3: 2003)	No genotoxic effects observed	

## **5.10 Summary**

It has been shown in this 510(k) submission that Dental Lithium Disilicate Glass Ceramic Block (Up. Press Series and Up. CAD Series) and its predicate devices have very similar indications for use, similar composition and biocompatibility, similar manufacturing process, and similar performance.

The difference between the subject device and its predicate device do not raise any question regarding its safety and effectiveness.

Dental Lithium Disilicate Glass Ceramic Block (Up. Press Series and Up. CAD Series), as designed and manufactured, are substantially equivalent as its predicate device.