DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 22, 2014

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

Re: K141723
Trade/Device Name: Upcera Coloring Liquid (I and II)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: July 24, 2014
Received: July 24, 2014

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,

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 K141723

Device Name: Upcera Coloring Liquid (I and II)

Indications for Use:

Upcera Coloring Liquid (I and II) is a liquid used for the complete or partial coloration of milled Upcera zirconia substructure and anatomy before sintering.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

## 5.1 Submitter & Foreign Manufacture Identification

Liaoning Upcera Co., Ltd
No.122 Xianghuai Road, Economic Development Zone, Benxi, Liaoning, China
Tel: (086) 24-5565055
Submitter's FDA Registration Number: 3010582952
www.upcera-dental.com

## 5.2 Contact Person

Charles Shen
Manton Business and Technology Services
853 Dorchester LN, Unit-B
New Milford, NJ 08534
Tel: 608-217-9358
Email: cyshen@aol.com

**5.3 Date of Summary:** May 15, 2014

**5.4 Device Name:**

| | |
|---|---|
| **Proprietary Name:** | Upcera Coloring Liquid (I and II) |
| **Common Name:** | Coloring Liquid |
| **Classification Name:** | Powder, Porcelain |
| **Device Classification:** | II |
| **Regulation Number:** | 21 CFR 872.6660 |
| **Panel: General** | Dental |
| **Product Code:** | EIH |

## 5.5 Predicate Device Information:

(1) K123680, "CopranClor", manufactured by "White Peaks Dental Systems Gmbh & Co. KG." located in Essen, Germany

## 5.6 Device Description:

Upcera Coloring Liquid (I and II) are water based coloring liquids, which consist of watery, acidic metal salt solutions. They are used for the individual staining of dental zirconia frameworks and restorations prior to the final sintering of the restoration, enabling the user to adjust the restoration to match the natural color of the patient's teeth.

Upcera Coloring Liquid I is provided in 21 different shades, and Upcera Coloring Liquid II is provided in 16 different shades, which are corresponding to patient's closest tooth color. For staining, the zirconia materials have to be immerged into the liquids or to be brushed with the liquids, prior to sintering at high temperatures.

### 5.7 Intended Use:

Upcera Coloring Liquid (I and II) is a liquid used for the complete or partial coloration of milled Upcera zirconia substructure and anatomy before sintering.

### 5.8 Summary of Device Testing:

Bench testing was performed to ensure that the Upcera Coloring Liquid (I and II) 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 Substantial Equivalence Discussion

Upcera Coloring Liquid (I and II) is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K123680, "CopranClor", manufactured by "White Peaks Dental Systems Gmbh & Co. KG." located in Essen, Germany

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 | Our Device (Upcera Coloring Liquid I and II) | Predicate Device (K123680) |
|---|---|---|
| Indication for Use | Upcera Coloring Liquid (I and II) is a liquid used for the complete or partial coloration of milled Upcera zirconia substructure and anatomy before sintering. | CopranColor is intended to be used as the coloring agent for the shading of white zirconia ceramic materials that are to be used by professional dental technicians to fabricate all-ceramic dental restorations for dental patients. |
| Technology | Water based with inorganic pigments | Water based with inorganic pigments |
| Operating Principle | Brush or immerse zirconia ceramic materials with coloring liquid before sintering | Brush or immerse with zirconia ceramic material before sintering |
| Ingredient | Upcera Coloring Liquid I:<br>Water, Polyethylene glycol, HCl, | Water, Polyethylene glycol, inorganic salts |

| | | |
|---|---|---|
| | inorganic salts<br>Upcera Coloring Liquid II:<br>Water, Polydextrose, inorganic salts | |
| Bottle Size | Various | Various |
| Shade | Various | Various |
| Prescription | Yes | Yes |
| Sterile | Non-sterile | Non-sterile |

Our device is similar to the predicate device in terms of indications for use, technology, and principle of operation. It is similar with predicate device that water and inorganic pigments are the main ingredients.

The indication for use of the subject device is phrased differently than the predicate device for business reasons. However, both share exactly the same expected use: as coloring agent for shading of dental zirconia blanks. Same as predicate device, the subject device is also restricted to professional dental technicians, as illustrated on its product label.

There are some minor differences between Upcera Coloring Liquid I and the predicate device. First, the predicate device does not contain acid (HCl). HCl will be evaporated with no residue left at the sintering step after the coloring liquid is applied to the zirconia ceramics, so it will not cause any effect to the patients. Second, Upcera Coloring Liquid I uses different inorganic pigments (metal nitrates). This will not raise any safety issues as the metal nitrates we use all have long established safety profiles, and we have conducted biocompatibility testing with the products.

There are minor differences between Upcera Coloring Liquid II and the predicate device. First, the predicate device does not contain Polydextrose. Polydextrose is an indigestible synthetic polymer of glucose. It is a food ingredient classified as soluble fiber by the U.S. Food and Drug Administration, so it will not cause any effect to the patients. Second, Upcera Coloring Liquid II uses different inorganic pigments (metal nitrates). This will not raise any safety issues as the metal nitrates we use all have long established safety profiles, and we have conducted biocompatibility testing with the products.

The following table shows similarities and differences of the key performance between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in USP or ISO 10993-1, and results met all relevant requirements in the test standards, and are comparable to the predicate device.

**Table 5.2: Comparison of Performance Testing**

| Description | Our Device (Upcera Coloring Liquid I and II) | Predicate Device (K123680) |
|---|---|---|
| Heavy Metals (USP) | Pb ≤10mg/kg, Cd ≤ 3mg/kg, Hg ≤2mg/kg, As ≤2mg/kg, Cr ≤2mg/kg | Information not available |
| Cytotoxicity (ISO 10993-5:2009) | No cyteotoxicity effect | Claims biocompatible in general |
| 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 | |

Therefore, the Upcera Coloring Liquid (I and II) manufactured by "Liaoning Upcera Co., Ltd." meet requirements per internal standard, USP, ISO 10993-1. It is safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses. The test results are also comparable to the predicate device.

## 5.10 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that Upcera Coloring Liquid (I and II) and its predicate devices have the similar indications for use, technology, principle of operation, similar composition, performance, and biocompatibility.

The difference between Upcera Coloring Liquid (I and II) and its predicate device do not raise any question regarding its safety and effectiveness.

Upcera Coloring Liquid (I and II), as designed and manufactured, are as safe and effective as its predicate device, and therefore are substantially equivalent as its predicate device.