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

March 14, 2017

Itena Clinical
% Louis-Paul Marin
President
Lok North America Inc.
2025 Rue Michelin
Laval, H7L 5B7
CANADA

Re: K162960
Trade/Device Name: TotalC-RAM
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: December 19, 2016
Received: December 27, 2016

Dear Louis-Paul Marin:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Susan Runner DDS, MA

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
TOTALC-RAM

Indications for Use *(Describe)*
It is intended for the permanent cementation of ceramic (including zirconia), composite and metal-based posts, crowns, bridges, veneers, inlays and onlays.

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.

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## Abbreviated 510(k) Summary

**1. Name/Address of Submitter:** **Itena Clinical**

**2. Contact Person:** **Louis-Paul Marin**
LOK North America Inc.
Phone: (514) 928-5546
Email: marin.lp@lok-corporation.com

**3. Date Summary Prepared:** October 12th, 2016

**4. Devices Names:** TotalC-Ram

**5. Device Classification:** II, 21 CFR 872.3275

**6. Common name:** Dental Cement

**7. Classification Product Code:** EMA

**8. Predicate Devices:**

| | |
|---|---|
| **TotalCem** | **K121804** |
| **DentoCem** | **K121804** |

**9. Devices Description:**

TotalC-Ram is permanent, radio-opaque dual cured (auto/photopolymerizable) self-etch and self-adhesive resin cement. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate devices:

| **Chemical Composition:** | **Subject Device** | **Predicates TotalCem** | **Predicates DentoCem** |
|---|---|---|---|
| Matrix: | UDMA<br>Bis-GMA<br>TEGDMA | UDMA<br>Bis-GMA<br>TEGDMA | UDMA<br>Bis-GMA<br>TEGDMA |
| Fillers | Barium Glass<br>Fumed Silica | Barium Glass<br>Fumed Silica | Barium Glass<br>Fumed Silica |

| **Physical/Mechanical Properties:** | **Subject Device** | **Predicates TotalCem** | **Predicates DentoCem** |
|---|---|---|---|
| Delivery | Automix | Automix | Automix |
| Curing Method | Light Self-Cure | Light Self-Cure | Light Self-Cure |
| Radiopacity (% Al) | Yes | Yes | Yes |
| Shear Bond Strength to Zirconia (MPa) | 11.2 | 2.8 | 3.8 |
| Flexural strength (MPa) | 125.5 | 170 | 151 |
| Solubility (µg/mm3) | LOW | LOW | LOW |
| Working time at 22ºC (min) | 4.5 | 4 | 2.5 |
| Setting time at 37 ºC (min) | 2.5 | 3 | 4 |
| Film thickness (µg/mm3) | 10 | 10 | 10 |
| Shelf life (Years) | 2 | 2 | 2 |
| Shear Bond Strength to Zirconia (MPa) | 11.2 | 2.8 | 3.8 |

TotalC-Ram is similar to the predicate devices in that they are all auto-mixing, dual-curing, radio-opaque, self-etch and self-adhesive resin cements to be used for permanently cementing restorations such as posts, crowns, bridges, inlays and onlays.

The subject device and the predicate devices have substantially equivalent physical and mechanical properties. As depicted above, the values for the shear bond strength between the subject device and zirconia demonstrate significantly higher values for the subject device. The indication for use for TotalC-Ram mentions specifically the use for ceramics cementation (including zirconia). The differences in the indications for use affect neither the intended use nor substantial equivalence.

TotalC-Ram is different from the predicate devices in that it contains the same key biocompatible ingredients, but in different proportions. The differences in the indications for use affect neither the intended use nor substantial equivalence.

**10. Indication for Use:**

The device is intended for the permanent cementation of ceramic (including zirconia), composite and metal-based posts, crowns, bridges, veneers, inlays and onlays. Below is a comparison of the indications for use of the subject device and the predicates:

| | **Subject Device (Shade Dentin Base)** | **Predicate Device TotalCem** | **Predicate Device DentoCem** |
|---|---|---|---|
| Indication for use: | for the permanent cementation of ceramic (including zirconia), composite and metal-based posts, crowns, bridges, veneers, inlays and onlays | for the cementation of posts, crowns, bridges, inlays and onlays. | intended for permanent cementation of:<br>crowns and bridges, inlays, onlays, posts and cores, ceramic crowns, Maryland bridges and veneers;<br>implant prosthesis;<br>orthodontic attachments;<br>amalgam restorations;<br>veneering of alloys; and<br>composite restorations. |

The indication for use for TotalC-Ram mentions specifically the use for ceramics cementation (including zirconia) as this device demonstrate significantly higher shear bond strength values when used for ceramic cementations. The differences in the indications for use affect neither the general intended use nor substantial equivalence.

**11. Brief Description of Performance and Biocompatibility Testing:** This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications". In support of this, Itena Clinical has provided information to establish substantial equivalent to the predicates and demonstrate conformity with FDA's guidance document entitled Dental Cements – Premarket Notification, August 1998 and the following recognized consensus standards:

- ISO 4049 – Dentistry – Dentistry -- Polymer-based restorative materials;
- ISO 7405 - Dentistry – dentistry - evaluation of biocompatibility of medical devices used in dentistry;
- ISO 9917-1 - Dentistry-- water-based cements - part 1: powder/liquid acid-base cements; and
- ISO 10993-5 - Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity.

TotalC-Ram meets or surpasses requirements set forth therein, notably as regards flexural strength, solubility, film thickness and radiopacity.

**12. Clinical Performance Data**

Not applicable. Clinical performance testing has not been performed for the subject device.

**13. Conclusion Drawn:** Based on a comparison of intended use and indications for use, physical properties and chemical composition, Itena Clinical concludes that the subject device is substantially equivalent to the predicates (respectively, TotalCem and DentoCem (**K121804)**).