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

3M Deutchland GmbH
Ruediger Franke
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Seefeld, Bavaria 82229
GERMANY

September 1, 2016

Re: K161922
Trade/Device Name: XP202
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: August 26, 2016
Received: August 29, 2016

Dear Mr. Ruediger Franke:

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" (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 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
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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
XP202

Indications for Use *(Describe)*

- Single crowns
- Bridges with a maximum of one pontic between two crowns
- Inlays, onlays, and veneers

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.

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510(k) Summary K161922

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Trade Name: XP202

Common Name: ..... Zirconia Blank

Classification Name:..... Porcelain powder for clinical use
..... (21 CFR 872.6660, product code EIH)

Device Class: ..... Class II

Primary Predicate Device ..... Katana STML (K143439)

Reference Predicate Devices ... Lava Plus – Mill Blanks and Dyeing Liquids (K011394)
..... Lava Plus – Effect Shades (K120011)

Description of Device

XP202 zirconia blanks are used for the fabrication of esthetic zirconia restorations. The blanks are available in various heights and shades based on the Vita™ Classical shade guide. After sintering, restorations display a gradient shading and inherent fluorescence. The restorations are designed using dental CAD software and the data is converted into milling paths by CAM software. The blanks can be processed in milling units suitable for pre-sintered zirconia. Milled restorations must be final sintered in a furnace suitable for zirconia per the cycle designated for XP202.

Applicable Standards for Product Tests

- ISO 6872: Dentistry — Ceramic materials

Indications for Use for XP202

- Single crowns
- Bridges with a maximum of one pontic between two crowns
- Inlays, onlays, and veneers

Comparison

Chemical composition, performance, fundamental technology, and intended use of XP202 have been compared to the predicate devices.

The tables below summarize the indications and technology of XP202 and predicate devices:

XP202	Katana STML (K143439)	Lava Plus Blanks and Dyeing Liquids (K011394)	Lava Plus Effect Shades (K120011)
• Single crowns • Bridges with a maximum of one pontic between two crowns • Inlays, onlays, and veneers	KATANA Zirconia is used for the fabrication of the all-ceramic restorations (frameworks, FCZ crowns, FCZ bridges, Inlays, onlays and veneers)	The LAVA™ system is intended for CAD/CAM fabrication of all-ceramic dental restorations. The system is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.	Lava Plus Effect Shades are suited for more intensive coloring of Lava Plus zirconia frameworks and Lava Plus all-zirconia restorations after basic dyeing using lava Plus Dyeing Liquids

Table Comparison of indications

Technology	XP202	Katana STML (K143439)	Lava Plus (K011394) (K120011)
Zirconia Mill Blanks	x	x	x
Shading	Preshaded Blanks	Preshaded Blanks	Unshaded Blanks (K011394) with dyeing liquids (K011394) and effect shades (K120011) as shading solutions

Table Comparison of technology

XP202, Kanata STML and Lava Plus are zirconia mill blanks with ZrO2 as the mean component. 3M Deutschland GmbH provided information to FDA about the composition of XP202 and compared this with chemical analysis of the predicate devices.

In vitro testing was conducted to show that XP202 fulfils the requirements of FDA recognized standard ISO 6872. Additionally, the performance of XP202 was compared to the predicate devices Katana STML and Lava Plus regarding flexural strength, chemical solubility and linear thermal expansion. The results of XP202 are similar to Katana STML. The difference between XP202 and Lava Plus are their flexural strength and is addressed by limiting the indications to three unit bridges according ISO 6872. In summary, 3M Deutschland GmbH concludes that XP202 is substantially equivalent to the predicate devices regarding performance and physical properties.

Biocompatibility

The biocompatibility assessment for this product was conducted in accordance with the following guidance:

1) Testing guidelines outlined in the FDA General Program Memorandum G95.
2) ISO 10993-1 :2009(E) Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process; in addition, relevant detailed guidance in ISO Standards 10993-3:2014 (Tests for genotoxicity, carcinogenicity and reproductive toxicity), 10993-5:2009 (Tests for in vitro cytotoxicity), 10993-10:2010 (Tests for irritation and skin sensitization); and 10993-11:2006 (Tests for systemic toxicity) was considered;
3) ISO 7405:2008/ Amd 1: 2013 Dentistry-- Evaluation of Biocompatibility of Medical Devices in Dentistry;

The biocompatibility of XP202 has been assessed by a board-certified toxicologist according to recommendations in FDA guidance and internationally recognized standards for medical and dental devices. The conclusion of the assessment is that XP202 is safe for its intended.

Conclusion

Comparisons of the indications for use/intended use, composition, technology, and physical properties showed that XP202 does not raise any new questions about safety and effectiveness and is substantially equivalent to the predicate devices.