K130654

510(k) Summary

DENTAL LABORATORY MILLING SUPPLIES

Submitter	Dental Laboratory Milling Supplies, LLC (DLMS) 14201 N 87th Street #A-105, Scottsdale, AZ 85260
Contact	Scott Atkin, President, 480-948-0466 email: scott@dentalzirconia.com
510(k) Number	K130654
Date Prepared	Revised on September 9, 2013 Original submitted on Feb 11, 2013
Trade/Device Name	Crystal® Ultra
Common Name	Dental CAD/CAM Material
Classification Names	Porcelain Powder for Clinical Use (21 CFR 872.6660, Product Code EIH) Tooth Shade Resin Material (21 CFR 872.3690, Product Code: EBF)
Predicate Device(s)	"Lava Ultimate CAD/CAM Restorative for CEREC/ E4D, Lava Ultimate Implant Crown Restorative," K110131, dated 1/21/11, and Vita "Enamic," K122269, dated 12/13/12
Device Description	The Crystal® Ultra CAD/CAM formed materials consist of interpenetrating networks of glass ceramic and polymer material to form a solid block of material. The unique marriage of the two materials creates a dual-network hybrid, which lends the positive physical properties of each individual material to the other. This results in a material with significantly lower brittleness compared to a pure ceramic and better abrasion behavior than a pure resin, (similar to natural enamel). The material is milled in a dental CAD/CAM machine into its restorative form.
Statement of Intended Use	Crystal® Ultra is indicated for use as a dental restoration including inlays, onlays, veneers, crowns, and bridges.
Substantial Equivalence	Information provided in this application shows that the product is substantially equivalent to the predicate devices. Both Crystal® Ultra and the predicate devices are composite ceramic and resin materials. The blending of these two proven dental materials creates beneficial physical properties while remaining compliant to the FDA recognized consensus standards applied to these material types. Bench testing was performed on Crystal® Ultra in accordance to FDA recognized standards and compared to predicate devices as per ISO 6872, ISO 10477, ISO 10993, ISO 4049, and ISO 7405, including bench testing and comparative analysis of flexural strength, chemical solubility, elasticity, compressive strength, density, water absorption, shade stability, color consistency, and water solubility. Comparisons of the physical properties of the Crystal® Ultra to the predicate devices are included in this application, which illustrate that they are substantially equivalent.
Design Characteristics	The geometry of the Crystal® Ultra material is shaped into block or disc forms as defined by the CAD/CAM manufacturer. The material will be inserted in to the CAM machine and milled into its final form, then polished and ready for placement thereafter.

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Material Characteristics	The majority volume of the Crystal® Ultra material is made up of a ceramic material similar to the predicate devices and used commonly in dentistry. The remaining volume of the block is made up of resin. This combination of ceramic and resin material is similar to the Vita Enamic and Lava Ultimate predicates. Comparisons of the material composition to the two predicates to the Crystal® Ultra are included in this application.
Biocompatibility	An assessment of the biocompatibility of the new device was performed, based on FDA Recognized ISO 10933 standards. This assessment, included in this application, concluded that the device substantially equivalent in safety (and effectiveness) to the predicate device.
Non-Clinical Performance Data	Bench testing was performed in accordance to FDA recognized standards ISO 6872, ISO 10477, ISO 7405, and ISO 4049 which includes ISO testing of flexural strength, solubility, radioactivity, storage stability, color stability, color consistency, plus additional evaluation of bond strength, modulus of elasticity and compressive strength. The results of this testing allowed us to conclude that Crystal® Ultra is substantially equivalent in safety (and effectiveness) to the predicate device. Test results are included in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 24, 2013

Dental Laboratory Milling Supplies, LLC
C/O Mr. Scott Atkin
President
14201 North 87th Street, Suite A-101
Scottsdale, AZ 85260

Re: K130654
Trade/Device Name: Crystal® Ultra
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH, EBF
Dated: August 20, 2013
Received: August 26, 2013

Dear Mr. Atkin:

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.

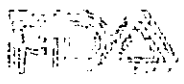
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Richard C. Chapman

for

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130654

Device Name: Crystal Ultra

Indications for Use:

Crystal® Ultra is indicated for use as a dental restoration including inlays, onlays, veneers, crowns and bridges.

For use by or on the order of a dental professional.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.09.24 11:35:48 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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