January 31, 2020

Qinhuangdao Audental Metal Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401 CHINA

Re: K192535
Trade/Device Name: Unshaded Dental Zirconia and Pre-Shaded Dental Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: November 1, 2019
Received: November 4, 2019

Dear Ray Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Digitally signed by Michael E. Adjodha -S
Date: 2020.01.31 13:48:14 -05'00'

for Srinivas "Nandu" Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60145841 0001

Report No.: 50305865 002

Manufacturer:
Audental Bio-Material Co., Ltd.
2-2, 88 Jingche Road, Songjiang District
201611 Shanghai
P.R. China

Products:
-Dental Alloys
-Dental Zirconia Ceramics

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-01-21

Date: 2020-01-21

Notified Body

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

AUDENTAL SLM POWDER

AUDENTAL® Cobalt

Dental Cobalt-Chrome Alloy for Porcelain

Co	Cr	Mo	W	Si
61,5%	28,1%	5,3%	5,0%	1,0%

Mn, Fe <1%

15~45 µm

ISO 22674 ISO 13485 CE 0197 FDA

Lot

NET Wt(g)

Cobalt

PRODUCT NAME: Audental Cobalt
DESCRIPTION: Cobalt based dental laser sintering alloy, type 5
GRAIN SIZE: 15 – 45µm
Manufacturer: Audental Bio-Material CO., Ltd.
Address: 2-2 88, Jingche Road, Songjiang District, Shanghai, P.R.China.
EC REP: Lotus NL B.V. Tel:+31645171879
EC REP Add.: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Post: 201661 **Tel:** 021-37727922
APPLIED: ISO 22674:2006, ISO 9693-1 , Manufacturer is certified according to ISO 13485:2003 / ISO 9001:2008 with appendix V MP-guideline 93/42/EEC
CHEMICAL COMPOSITION:
Co:61.5%, Cr:28.1%, Mo:5.3%, W:5.0%, Si:1.0%, Mn, Fe<1.0%
TECHNICAL DATA
Yield strength 0,2 %: >500MPa Elongation:14,7 % Density: 8.55 g/cm³
Tensile strength: 525 MPa E-module: 240 GPa Tarnish resistance:yes
Corrosion resistance:< 200 µg/cm² CTE (25 – 500°C): 14.5 x $10^{-6}K^{-1}$
Hardness:365 HV 10 Melting Range: 1350-1385℃
Indication: Crowns and bridges, implant supported superstructures and bars.
Thermal treatment
After the laser sintering process, the building boards have to pass heat treatment to minimize stresses due to the laser sintering process. For this purpose,a suitable furnace with inert gas (argon) or vacuum function should be used. Stress relieving without inert gas atmosphere can optionally be performed.Please consider that a treatment without inert gas atmosphere can lead to an increased oxide formation. Heat up to 460°C with inner gas within 60 min to keep 45mins, heat up to 750°C with inner gas within 45 mins to keep 60 mins, Cooling to 600, then open door, Cooling to 300, then take out.