K093571

Ams Co., Ltd.

1284-3 Joungwang-dong, Siheung-si, Kyunggi, Korea (429-850)
Tel: *82-31-4311751 Fax: 082-31-4021751

MAR 12 2010

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: Ams Co., Ltd.
1284-3 Joungwang-dong, Siheung-si, Kyunggi, Korea
Tel: *82-31-4311751 Fax: 082-31-4021751

Date Summary Prepared: Feb 19, 2010

Contact Person: Tae Choung Son / president
info@ams.bz

Device Name:
Trade Name(s): Zr Dental block
Classification Name: Porcelain Powder for Clinical Use
Panel: Dental
Product Code: EIH

Predicate Device Information:
K083201 Zmatch Block manufactured by Dentam Company, Limited

Device Description:
Dental Porcelain Zr Dental block is composed of ZrO_2, HfO_2, Y_2O_3, Al_2O_3 and other material (SiO_2(≤0.16%), Fe_2O_3(≤0.05%), TiO_2(≤0.04%), MnO_2(≤0.002%), Na_2O(≤0.001%) and they are intended for use by dental technicians for dental prothesis.

Intended Use:
Zr Dental block is intended for CAD/CAM fabrication of all ceramic dental restorations. This device is used for manufacturing of inlays, onlays, veneers, crowns and bridges

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in intended use and technological characteristics, including:

*components
*indications for use
*chemical properties
*performance properties

Conclusions:
Based on the information provided in this premarket notification Ams Co., Ltd concludes that Zr Dental block is safe and effective and substantially equivalent to predicate device as described herein.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR 12 2010

AMS Company, Limited
C/O Mr. Claude Yang
Chief Executive Official
Onbix Corporation
#708 Le-Meilleur Town, 837-19 Gangnam-Gu
Seoul
Republic of Korea 135-937

Re: K093571
Trade/Device Name: Zr Dental Block
Regulation Number: 21CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: February 28, 2010
Received: March 9, 2010

Dear Mr. Yang:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093571

Indications for Use

510(k) Number (if known): _____

Device Name: Zr Dental block

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz DDS for Dr. K.P. Mulay

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

510(k) Number: K093571

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