

K120471 : Device: Orthodontic Ceramic Bracket

JUN - 4 2012

See 510(k) Summary, below.

1. Trade Name: . MACH BRACKETS, BRIGHT BRACKETS
Common Name: Orthodontic Ceramic Bracket
Classification Name: Bracket, Ceramic, Orthodontic, product code NJM
Product Code: NJM
Regulation: 872.5470
Class of device : Class II.

1. The legally marketed device to which we are claiming equivalence:
Orthodontic Ceramic brackets (K090933)

2. Description of device:

The MACH BRACKETS are bonded to teeth to apply pressure to the tooth, transmitted through a flexible orthodontic wire, to alter the tooth position.

The modified orthodontic ceramic bracket has both aesthetic and self-ligating qualities. The modifications were aimed at facilitating easier orthodontic wire placement and removal through self-ligation and enhancing the bonding and debonding characteristics of the bracket.

3. Intended Use :

The device is intended for orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single used only.

4. Technological Characteristics:

The MACH BRACKETS is produced using Al₂O₃, translucent polycrystalline aluminum oxide (99.99%).

This MACH BRACKETS are bonded to the teeth with commercially available materials and linked together by "arch wire" that applies steady, gentle pressure to produce desired tooth movement

5. Performance: Bench tests were performed.

Biocompatibility as follows;

Test Items		Test method	Tested by	Test results
Biocompatibility Tests	In vitro cytotoxicity	ISO10993-5	Dental Devices Testing & Evaluation Center Yeonsei University, College of Dentistry	Passed
	Oral mucous membrane irritation test	ISO10993-10		Passed
	BrdU' as a fuideline for testing skin sensitization	ISO10993-10		Passed

The tests demonstrated that the device is as safe, as effective and performs in a substantially equivalent manner to the predicate device.



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

World Bio Tech Company, Limited
C/O Mr. Peter Chung
Correspondent
300 Atwood Street
Pittsburgh, Pennsylvania 15213

JUN - 4 2012

Re: K120471
Trade/Device Name: Mach Brackets, Bright Brackets
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: April 28, 2012
Received: May 9, 2012

Dear Mr. Chung:

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.

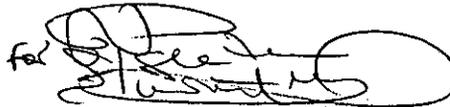
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", is written over a circular stamp or seal.

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

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K 12 0 4 7 1

Device Name: Orthodontic Ceramic Bracket.

Indications For Use:

The device is intended for orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. The devices are intended to be single used only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K120471

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