K102561

5. 510(k) Summary
(per 21 CFR 807.92)

JAN 25 2011

I. Applicant

Name : HT Co., Ltd.
Address : HBI 513, Hanyang Univ., 1271, Sa3-dong, Ansan-si, Gyeonggi-do, 426-791, Korea

Contact Person: Jerry Choi Manager
(Tel : 82-31-400-3932 Fax : 82-31-418-2803)

Date Prepared: Sep 6th, 2010

II. Device Name

Proprietary Name:	MISO Translucent Orthodontic Bracket
Common/ Usual Name:	Orthodontic Plastic(Ceramic) Bracket
Classification Name:	Orthodontic appliance and accessories
Regulation Number:	21CFR872.5470
Product Codes:	NJM
Classification:	II
Classification Panel:	Dental

III. Predicate Device

MISO Translucent Orthodontic bracket is substantially equivalent to the Absolute bracket from Star Dentech Korea, Corp. and the Pure bracket from Ortho Technology. The Absolute bracket was most recently cleared by the FDA on May 27, 2009 under 510(k) K090567. The Pure bracket was cleared by the FDA on December 18, 2007 under 510(k) K073045.

IV. Indications for use statement

MISO Translucent Orthodontic Bracket is indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

V. Description of the Device

MISO Translucent Orthodontic Bracket is comprised of single crystal(mono clear sapphire) alumina. The translucent properties of the bracket make the bracket less visible than polycrystalline ceramic and metal brackets. MISO Translucent Orthodontic Bracket consists of 3parts. The bracket consists of three distinct parts: (1) arch wire slot, (2) four tie wings, and (3) base. The arch wire slot allows the placement of an arch wire which applies the necessary force to effect tooth movement. The tie wings allow the placement of an elastic o-ring, which holds the arch wire in place. The base is adhered to a patient's tooth using adhesive, thereby anchoring the bracket to the tooth.

VI. Summary of the Technical Characteristics

MISO Translucent Orthodontic Bracket was designed and tested using the following standard:

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- ISO 11405:2003 - Dental materials -- Testing of adhesion to tooth structure

VII. Conclusion of Safety & Effectiveness

There are no known substantial differences between the bracket defined in this 510(k) submission and the predicate devices. They have the same intended use and any differences in technological characteristics do not raise issues of safety and effectiveness.

Company	**Star Dentech**	**Ortho Technology (OEM : Hubit)**	**HT Co., Ltd**
Product Name	*Absolute*	Sapphire Ceramic Bracket	MISO
510(k) Number	K090567	K073045	
Product Code(s)	NJM	NJM	NJM
Regulation #	21CFR872.5470	21CFR872.5470	21CFR872.5470
Class	II	II	II
Intended Use	Movement of teeth	Movement of teeth	Movement of teeth
Material Composition	Alumina(mono crystal ceramic bracket)	Alumina(mono crystal ceramic bracket)	Alumina(mono crystal ceramic bracket)
Translucent	Yes	Yes	Yes
Standards	ISO 10993 biocompatibility	ISO 10993 biocompatibility	ISO 10993 biocompatibility
Biocompatibility	Yes	Yes	Yes
Available Slot Sizes	0.018 /0. 022 inch	0.018 /0. 022 inch	0.018 /0. 022 inch
Available Prescriptions	Roth / MBT / Edgewise	Roth / MBT / Edgewise	Roth / MBT / Edgewise
Bond Strength* (MPa)	5.51 ± 1.65	19.41 ± 5.08	11.73 ± 3.04

*Bond strength testing was carried out according to ISO 11405-2003(E).
Results are detailed in Section 12.

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

Mr. Jerry Choi
Manager
HT Company, Limited
HBI 513, Hanyang Univ., 1271, Sa3-dong
Ansan-si, Gyeonggi-do
426-791, Korea

JAN 25 2011

Re: K102561
Trade/Device Name: MISO Translucent Orthodontic Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthondontic Appliance and Accessories
Regulatory Class: II
Product Code: NJM
Dated: January 13, 2011
Received: January 13, 2011

Dear Mr. Choi:

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

K102561

4. Indication for Use Statement

510(k) Number (if known): K102561

Device Name: MISO Translucent Orthodontic Bracket

Indications for Use:

MISO Translucent Orthodontic Bracket is indicated for orthodontic movement of natural teeth, excluding mandibular bicuspid teeth.

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

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

510(k) Number: K102561