510(k) Summary EBI Internal Implant K073116

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.93

Submitter	EBI Inc. #289, Wuisong-ri, Apryang-myeon Kyeongsan-city, Kyeongsangbook-do 712-825, Korea Telephone 82-53-817-7767 Fax: 82-53-817-7768
Contact	Myung-bae Jegal, Managing Director
Date Prepared	February 21, 2008
Device Name	EBI Internal Implant
Classification Name	Implant, endosseous, root-form DZE and Abutment implant, dental, endosseous NHA
Device Classification	Class II Dental Devices Panel 21 CFR 872.3640 and 872.3630
Predicate Devices	• AVANA Dental Implant System K051576 • ITI Dental implant system K003552
Performance	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug, and Cosmetic Act.
Device Description	The EBI Internal Implant system is a threaded, root form endosseous implant comprised of an internal octagon, 8° morse tapered device manufactured from pure Titanium ASTM F-67 and the Abutment from Titanium 6A-4V alloy E 11 –ASTM 136. The implant's external threaded surfaces are roughened to facilitate tissue and bone integration. The implant's self-tapping feature may be used with or without pre-tapping the bone. System components for restorative purposes include: screw retained and cement retained abutments, cover screws, healing abutments, and angled abutments.
Indications for Use	EBI dental implants are intended for immediate, delayed, or conventional placement in the maxillary and/or Mandibular arches to support crowns, bridges or overdentures in edentulous or partially edentulous patients.

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Technical Characteristics

Characteristics	EBI Internal Implant System	Predicate Devices: AVANA Dental Implant	Predicate Devices: ITI Dental Implant
510(k)	-	**K051576** OSSTEM Co., Ltd.	**K003552** Institut Straumann AG
Material composition	**Implant:** Pure Titanium **Abutment:** Ti Alloy	**Implant:** Pure Titanium **Abutment:** Ti Alloy	**Implant:** Pure Titanium **Abutment:** Ti Alloy
Design	Internal Morse Taper, Internal Octagon	Internal Connection Morse Taper, Internal Octagon	Internal Connection Morse Taper, Internal Octagon
Implant Diameter	3.3-4 mm	4.1-4.8 mm	3.3 – 4 mm
Implant Length	6-15 mm	8.4-15 mm	6 – 14mm
Sterilization Method	Gamma	Gamma	Gamma
Indications for use	Intended for immediate delayed or conventional placement in the maxillary and/or Mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.	Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support of fixed bridgework.	Intended for immediate, delayed, or conventional placement in the maxillary and/or Mandibular arches to support crowns, bridges or overdentures in edentulous or partially edentulous patients.
Surface treatment	Resorbable Blasting media (RBM)	Resorbable Blasting media (RBM)	Resorbable Blasting media (RBM)

Conclusion: In all respects, the EBI Internal Implants components are the equivalent of currently marked devices. They are made of the same materials and have similar dimensions and characteristics. This device is substantially equivalent in design, material, intended use and function to the products listed in the table above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

EBI, Incorporated
C/O Mr. Daniel Kamm
Principal Consultant
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K073116
Trade/Device Name: EBI Internal Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 21, 2008
Received: February 25, 2008

Dear Mr. Kamm:

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.

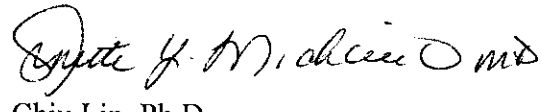
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K07

Device Name: EBI Internal Implant System

Indications For Use: Intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges or overdentures in edentulous or partially edentulous patients.

Prescription Use ✓ (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)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

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