K100902

## SECTION 4

**510 (K) SUMMARY AND CERTIFICATION (As required by 21 CFR 807.92 c)** JUN 24 2010

**March 30, 2010; amended June 8th, 2010**

**1. Submitter's Name and Contact person**

**EMBED Technology LLC** **Howard Stamer: Managing Member**

**9 East Main Street**

**Flemington NJ 08822** **T: 312 265 0065 (direct line) 908 782 3040 (general office)**

**2. General Information**

| | |
|---|---|
| **Trade Name** | **(Adams Embed Dental Implant System) AEDIS ™** |
| **Common Name** | **Endosseous Dental Implant System (screw type)** |
| **Classification Name** | **Endosseous implant** |
| **Device Classification** | **Class II** |
| **Product Code** | **DZE** |

**Identification of Predicate Device: Imtec 1.8 mm diameter implant K031106; (See too Intra-Lock 2 mm diameter implant K070602; Sendax MDI 1.8 mm diameter implants 3972351; K990983; and K023067.)**

**This submission is an abbreviated 510 (k) as discussed in the FDA's guidance document entitled "The New 510(k) Paradigm - Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications". Embed Technology LLC has provided information to demonstrate conformity with FDA's guideline document entitled *Endosseous Implants* 872-3640.**

**3. Device Description**

**The device is a Titanium alloy, root form implant system consisting of: a self-tapping 1.8 mm diameter implant screw with an integrated hexagonal fitment for attachment of an abutment, and a cap screw designed to lock the abutment to the implant screw. AEDIS™ abutments are not angled.**

AEDIS ™ follows natural tooth morphology and is recommended for use in mandibular and maxillary anterior locations for restoration applications. The screw diameter is 1.8mm and is offered in lengths of 13.5 and 15mm. A minimally invasive procedure allows for immediate placement, and temporization in single and multiple tooth restorations. The implant screws are self tapping.

A titanium abutment is provided and is intended to be mechanically affixed to the screw to hold a crown, bridge, or other prosthetic appliance. The prosthesis may be secured to the abutment by the use of adhesives or mechanically by the use of a screw. The abutment is cone shaped; 8 mm in height; has a hexagonal fitment to provide for the cap screw) to lock the abutment the implant screw. The 5 mm diameter of the base of the abutment is identical to the diameter of the top of the implant screw. When all elements of the system are attached to each other the tolerances between the parts are 3 microns or less.

Immediate loading is not recommended where there is inadequate stability. Immediate loading should occur when the position of the implant provides adequate bone quality and quantity to allow proper immediate mechanical stabilization of the self tapping screw into the bone, and where occlusal and lateral forces can be limited with appropriate occlusal design when splinted. Dietary restrictions may also be required by the surgeon performing the implant procedure.

AEDIS™ is offered in a kit including: implant components; surgical instruments; a tissue punch, leveling bit, and implant insertion instruments. The package also includes recommended surgical protocols, and illustration of recommended insertion techniques. The kit is packaged in a plastic container with appropriate labeling. The AEDIS ™ is delivered in sterile condition, however many practitioners also autoclave the device in their own operatories.

4 Indications for Use

AEDIS ™ provides a self tapping titanium screw indicated for immediate transitional splinting stability, or long term intra-bony applications such as fixation of new or existing crown, bridge or denture installations in partially or fully edentulous mandibles and maxillae.

Immediate loading is not recommended where there is inadequate stability. Immediate loading should occur when the position of the implant provides adequate bone quality and quantity to allow proper immediate mechanical stabilization of the self tapping screw into the bone, and where occlusal and lateral forces can be limited with appropriate occlusal design when splinted. Dietary restrictions may also be required by the surgeon performing the implant procedure."

**5. Substantial Equivalence Comparisons**

**EMBED has provided test results and related scientific data demonstrating the substantial equivalence of the IMTEC predicate device and AEDIS™.**

**The fundamental scientific technology of the device is identical with or very similar to the referenced predicate devices. All materials, processing methods, packaging and sterilization methods are identical with those commonly used in the industry and the predicate devices. The subject and the predicate devices are either identical or substantially equivalent in size and materials, and all offer an abutment system for restorations. The Imtec predicate device and AEDIS packaging inserts each provide a dentist with the surgical protocols for use; pictorial examples of placement; the locations for insertion of anterior and posterior implants. The subject device and the predicates are distributed only to licensed dentists and doctors. EMBED has provided test results demonstrating the substantial equivalence of AEDIS™ and the predicate device. The tests were performed at an independent, highly qualified laboratory who certified the accuracy of the test results.**

**Summary of the technological characteristics of AEDIS™ and the predicate device**

| | | |
|---|---|---|
| **Device Name** | **AEDIS™** | |
| **IMTEC 1.8 MDI implant** | | |
| **Product Code** | **DZE** | **DZE** |
| **510(k)** | **K 100902** | **K031106** |
| **Material** | **Titanium Alloy** | **Titanium Alloy** |
| **Biocompatibility** | **Biocompatible** | **Biocompatible** |
| **Sterility** | **Sterile** | **Sterile** |

**Intended use:** **Self tapping titanium threaded screws indicated for long term intra-bony applications. Additionally MDI may also be used for intra-radicular transitional application**

**There are no new issues of safety or effectiveness presented by the subject device.**

**CONCLUSION**

**The predicate devices and similar implants have not disclosed any safety or health risks. There is no difference in design, materials, or indicated use of the subject device and the cited predicate or similar devices.**

**Based on the indications for use; results of testing under third party supervision; technological characteristics and comparison to predicate devices, the Adams Embed Dental Implant System AEDIS ™ has been shown to substantially equivalent to the predicate device and therefore safe and effective for its intended use. No new or additional issue of effectiveness or risk to health is raised by the AEDIS™ 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

Embed Technology LLC
C/O Mr. Howard Stamer
161 East Chicago Avenue, Suite 37F
Chicago, Illinois 60611

JUN 24 2010

Re: K100902
Trade/Device Name: AEDIS ™
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 10, 2010
Received: June 10, 2010

Dear Mr. Stamer:

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

SECTION 1

# Indication for Use

**"AEDIS ™ provides a self tapping titanium screw indicated for immediate transitional splinting stability, or long term intra-bony applications such as fixation of new or existing crown, bridge or denture installations in partially or fully edentulous mandibles and maxillae.**

**Immediate loading is not recommended where there is inadequate stability. Immediate loading should occur when the position of the implant provides adequate bone quality and quantity to allow proper immediate mechanical stabilization of the self tapping screw into the bone, and where occlusal and lateral forces can be limited with appropriate occlusal design when splinted. Dietary restrictions may also be required by the surgeon performing the implant procedure."**

**510(k) Number (if known): K# 100902**

**Device Name: Adams Embed Dental Implant System (AEDIS™)**

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**Concurrence of CDRH Office of Device Evaluation** Susan Runner

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

**Prescription Use: -X**

**(per 21 CFR 801.109)**

510(k) Number: K100902