K053170

Implant Innovations, Inc.
510(k) Premarket Notification - PreFormance™ Post

510(k) Summary

FEB 1 2006

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

Submitter	Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410
Contact	Jim Banic Regulatory Affairs Specialist Implant Innovations, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6932 Fax. 561-514 6316 Email jbanic@3implant.com
Date Prepared	November 11, 2005
Device Name	PreFormance Post
Classification Name	Dental Abutments
Device Classification	Class II Dental Devices Panel 21 CFR § 872.3630
Predicate Devices	GingiHue Abutments -> K871954 GingiHue Pre-Angled Abutments -> K932123
Performance	Performance standards have not been established by the FDA under Section 514 of the Federal Food, Drug and Cosmetic Act.
Device Description	The PreFormance Post will be shaped similar to the currently marketed GingiHue Post. However, the PreFormance Post will be made of PEEK with a titanium insert. The posts will be available in straight and 15° pre-angled configurations. The collar height on the PreFormance Post will be 4mm and 6mm and the post

height will be 7mm.

Indications for Use

The PreFormance Abutment Posts are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. They are intended for use to support single and multiple unit prostheses in the mandible or maxilla for up to 180 days during endosseous and gingival healing. The prostheses can be screw or cement retained to the abutment.

Technological Characteristics

Substantial equivalence of the PreFormance Posts is based on:

1. Design features which are similar to the currently available GingiHue Posts. The PreFormance Posts are made of PEEK with a titanium insert

2. Performance testing. The proposed and currently marketed devices are identical in terms of size, biocompatibility, performance characteristics and basic design.

Performance Testing

Laboratory testing was conducted to determine device functionality and conformance to design input requirements, as well as FDA's *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*. Risk Analysis was conducted in accordance with ISO 14971.

Conclusion

The PreFormance Posts are equivalent to the GingiHue Posts which provide similar functionality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2006

Mr. Jim Banic
Regulatory Affairs Specialist
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K053170
Trade/Device Name: PreFormance Posts
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: January 13, 2006
Received: January 17, 2006

Dear Mr. Banic:

This letter corrects our substantially equivalent letter of February 1, 2006.

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 (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 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 continue 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indications for Use

510(k) Number (if known): K053170

Device Name: PerFormance Posts

Indications for Use:

The PreFormance Abutment Posts and Temporary Cylinders are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. They are intended for use to support single and multiple unit prostheses in the mandible or maxilla for up to 180 days during endosseous and gingival healing, and are for non occlusal loading of single and multiple unit provisional restorations. The prostheses can be screw or cement retained to the abutment.

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

Robert S Beto DDS for Dr Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(Division Sign-Off) Number K053170

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