JUL 21 2006

K061969

## 510(k) Summary of Safety and Effectiveness

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

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| **Submitter** | Implant Innovations, Inc.<br>4555 Riverside<br>Palm Beach Gardens, FL 33410 |
| **Contact** | Jim Banic<br>Regulatory Affairs Specialist<br>Implant Innovations, Inc.<br>4555 Riverside<br>Palm Beach Gardens, FL 33410<br>Tel. 561-776-6932<br>Fax. 561-514 6316<br>Email: jbanic@3implant.com |
| **Date Prepared** | July 3, 2006 |
| **Device Name** | PreFormance™ Abutment Posts and Temporary Cylinders |
| **Classification Name** | Endosseous Dental Implant Abutment |
| **Device Classification** | Class II<br>Dental Devices Panel<br>21 CFR § 872.3630 |
| **Predicate Devices** | PreFormance™ Posts -> K053170<br>PreFormance™ Temporary Cylinders -> K060291 |
| **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™ Abutment Posts and Temporary Cylinders will be made of the same material (PEEK) as the predicate PreFormance™ Posts and Temporary Cylinders. The posts will be available in both straight and 15° pre-angled configurations while the cylinders will be straight. The cylinders will have either a hexed or non-hexed connection. The hexed connection is for single unit prostheses while the non-hexed is for multi use. The posts and cylinders will connect to *3i*'s externally connected implants. |

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**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.

**Technological Characteristics**

The PreFormance™ Abutment Posts and Temporary Cylinders have the same technological characteristics as the currently available PreFormance™ Abutment Posts and Temporary Cylinders. The modification is solely in the connection to the implant. The predicate device mates with the internal connection implant design while the modified device mates with the external hexed implant design.

**Conclusion**

The PreFormance™ Abutment Posts and Temporary Cylinders are substantially equivalent to the legally marketed PreFormance™ Abutment Posts and Temporary Cylinders.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2006

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

Re: K061969
Trade/Device Name: PreFormance Posts
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 3, 2006
Received: July 12, 2006

Dear Mr. Banic:

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

Special 510(k) Premarket Notification
PreFormance™ Abutment Posts and Temporary Cylinders

# Indications for Use

510(k) Number (if known): K061969

Device Name: PreFormance 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Beltz DDS for Dr Susan Runner

...gn Off)
...of Anesthesiology, General Hospital,
...Control, Dental Devices

...ber K061969

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