Implant Direct™ LLC
www.implantdirect.com

K06 0063

CONFIDENTIAL
Legacy Abutment System

MAY 19 2006

510(K) SUMMARY

Company Name: Implant Direct LLC
Address: 27030 Malibu Hills Road
Calabasas Hills CA 91301
Telephone Number: (818) 444-3300
Fax Number: (818) 444-3408
Registration Number: 3001617766
Submitter's Name: Leslie Terry
Contact Person: Patty McMahon
Date Summary Prepared: January 5, 2006 – amended May 3, 2006

Classification Name: Abutment, Implant, Dental, Endosseous
Common/Usual Name: Endosseous dental implant abutment
Device Trade Name: Legacy Abutment System

The primary device used for comparison in this summary is the Screw-Vent Dental Implant System **(K011028)**.

1. Description:

The Legacy Abutment System consists of cement retained and screw-retained components. All abutments have the same identical interface diameters as the predicate abutments to function with the corresponding mating Screw-Vent Implants manufactured by Zimmer Dental. The cement retained abutments are offered in a straight body with a straight or scalloped prosthetic margin and in an angled body with a scalloped prosthetic margin. The screw-retained abutments are offered in different cuff diameters and heights to accommodate for the different implant interfaces and tissue heights.

2. Intended Use:

The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients.

The Legacy Abutment System is compatible with implants that have mating diameters, lead-in bevels, internal hex sizes, and 1-72UNF internal threads, as shown in the Zimmer Dental Tapered Screw-Vent Surgical Manual.

Implant Direct LLC will monitor the compatible implants for modifications to ensure future compatibility. In the event of any modification, Implant Direct LLC will either modify the Legacy abutment to ensure compatibility, or cease claiming compatibility to the modified Zimmer Dental Screw-Vent implants.

3. Technological Characteristics:

The Legacy abutments provide support for crowns, bridges, or overdentures in edentulous or partially edentulous patients for cement retained and screw retained restorations following the same preparation principals as the predicate devices. The Legacy abutments have similar technological characteristics and the same intended use as the predicate device. The Legacy abutments are packaged non-sterile for sale unlike the predicate devices packaged sterile. The Straight, Scalloped, and Angled Abutments are designed to function as a foundation for cemented restorations. The Screw-Retained abutments are designed to function as a foundation for screw-retained restoration.

4. Comparison Analysis:

The overall designs of the Legacy Abutment System are similar to the predicate devices. The following **Tables 1, 2, 3** summarize the predicate device comparison analyses with the Legacy Abutments.

Table 1: Legacy Cement Retained Straight and Scalloped Abutments

Technological Characteristics	**Legacy Straight and Scalloped Abutments**	**Predicate Device: Screw Vent Dental Implant System (K011028)**
Intended Use	To be used as a post to support the cemented prostheses	To be used as a post to support the cemented prostheses
Indication	For single or multiple restorations	For single or multiple restorations
General Design	Hex engaging post with a prosthetic margin	Hex engaging post without a prosthetic margin
Cuff Diameters	4.5, 5.7, and 6.5 mm	3.5, 4.5, 5.7, and 6.5 mm
Implant/abutment Interface diameters	3.5, 4.5, and 5.7mm	3.5, 4.5, and 5.7mm
Material	Titanium Alloy	Titanium Alloy
Packaging	Scalloped Abutments: Screw mount inside a vial closed with a cap Straight Abutments: The abutments are attached to a plastic transfer/holder engaged within an inner vial. The inner vial, along with a screw-mount containing the temporary coping, will be placed within a larger outer vial and closed with a vial cap.	Screw mount inside a vial closed with a cap
Sterilization	Non-sterile	Sterile

Table 2: Legacy Cement Retained Angled Abutments

Technological Characteristics	Legacy Angled Abutments	Predicate Device: Screw Vent Dental Implant System (K011028)
Intended Use	To be used as a post to support the prostheses	To be used as a post to support the prostheses
Indication	For single or multiple restorations	For single or multiple restorations
General Design	Hex engaging angled post with a prosthetic margin	Hex engaging angled post without prosthetic margin
Material	Titanium Alloy	Titanium Alloy
Packaging	Screw mount inside a vial closed with a cap	Screw mount inside a vial closed with a cap
Sterilization	Non-sterile	Sterile

Table 3: Legacy Screw Retained Abutments

Technological Characteristics	Legacy Screw-Retained Abutments	Predicate Device: Screw Vent Dental Implant System (K011028)
Intended Use	Screw retained restoration	Screw retained restoration
Indication	Multiple unit application	Multiple unit application
General Design	One-piece abutment that screws inside the implant	One-piece abutment that screws inside the implant
Material	Titanium Alloy	Titanium Alloy
Packaging	Attached to a plastic transfer/holder engaged within an inner vial. The inner vial, along with a screw-mount containing the temporary coping, will be placed within a larger outer vial and closed with a vial cap	Screw mount inside a vial closed with a cap
Sterilization	Non-sterile	Sterile

5. CONCLUSION

The evaluation of the Legacy Abutment System does not raise any additional concerns regarding safety and effectiveness and therefore is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2006

Ms. Leslie Terry
Implant Direct, LLC
27030 Malibu Hills Road
Calabasas Hills, California 91301

Re: K060063
Trade/Device Name: Legacy Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental implant
Regulatory Class: II
Product Code: NHA
Dated: May 3, 2006
Received: May 4, 2006

Dear Ms. Terry:

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

Indications for Use

510(k) Number (if known): **K060063**

Device Name: Legacy Abutment System

Indications for Use:

The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients.

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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 IF NEEDED)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices of CDRH, Office of Device Evaluation (ODE)

510(k) Number: K060063