SEP 2 9 2006

K061319

510(k) SUMMARY

Company Name: Implant Direct LLC
27030 Malibu Hills Road
Calabasas Hills CA 91301
Phone Number: 818 444-3300
Fax Number: 818 444-3408

Registration Number: 3001617766
Submitter's Name: Gerald A. Niznick, DMD, MSD
Contact Persons: Patty McMahon
Date Summary Prepared: May 10, 2006
Classification Name: Implant, Endosseous, Root Form
Regulation Description: Endosseous Dental Implant
Common/Usual Name: Endosseous Dental Implant and Abutment

Device Trade Name: Spectra-System

1. Predicate Devices:

The Spectra-System was compared to the following devices previously cleared through a 510(k) Premarket Notification:

Tapered Screw-Vent **(K013227)**
Screw-Vent Dental Implant System **(K011028)**
Astra-Tech Implants Dental System Immediate Function **(K041492)**
Nobel Biocare Groovy Implants **(K050258)**
Advent and SwissPlus Dental Implant Systems **(K011245)**
Nobel Biocare Replace One-Piece Implant **(K023952)**
Lifecore PrimaSolo One-Piece Implant System **(K050506)**

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2. Description:

The Spectra-System consists of eight tapered screw endosseous implant designs with the same external thread configuration consisting of double lead threads over the body of the implant and 2mm-2.5mm of quadruple lead mini-threads near the coronal portion of the implant. Seven of the implants (ScrewPlant, ScrewPlus, ScrewDirect, ScrewIndirect, ScrewRedirect, RePlus and Legacy) have the same tapered body design in 3 diameters (3.7mmD, 4.7mmD & 5.7mmD) and are provided in a range of lengths from 8mm to 16mm. These implants can be inserted utilizing the same surgical instrumentation provided for the Zimmer Screw-Vent Tapered Implants, with the exception that the 5.7mmD requires a 5.4mmD drill in place of Zimmer's 5.7mmD drill. In addition, the ScrewDirect one-piece implant is also available in a 3.0mmD for specific indications. The eigth implant of the Spectra-System, the RePlant, matches the tapered body dimensions and tri-lobe platform of the Nobel Biocare Tapered Replace implants and therefore can be inserted utilizing Nobel Biocare drills. All Spectra-System implants are provided with either a roughened surface created by blasting with a soluble blast media, or coated with Hydroxl Appatite media. The Spectra-System also offers a variety of prosthetic options and ancillary components for restoration of these implants as implants from Nobel BioCare, Zimmer Dental, and BioHorizon.

Intended Use:

510(k) Number: K061319

Device Name: Spectra Dental Implant System

Indications for Use:

The Spectra Dental Implant System consists of one-piece or two-piece implants for single-stage or two-stage surgical procedures that are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. They may be placed in immediate function if initial implant stability can be established.

The ScrewDirect 3.0mm implant is indicated for:

1. An artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.

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2. Multiple tooth replacements or denture stabilization.

The Screw Redirect implant is intended for support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of the partially edentulous maxillary jaw. It is indicated for immediate functional loading when four or more implants are splinted together in the endentulous upper or lower jaw.

4. Technological Characteristics:

The Spectra-System is substantially equivalent to the predicate devices; has comparable technological characteristics, identical intended use and are similar in terms of material, size, and basic design features.

5. Comparison Analysis:

The overall implant product designs of the Spectra System are similar to the predicate devices. **Tables 1, 2, 3, and 4** in the following pages summarize the predicate device comparison analyses for the implants within the Spectra-System.

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Table 1: Two-Stage Implants – ScrewPlant and Legacy

Technological Characteristics	ScrewPlant and Legacy Implants	Predicate Device: Tapered Screw-Vent (K013227)	Predicate Device: Astra-Tech Implants Dental System Immediate Function (K041492)
Intended Use	Intended for surgical implantation in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary attachment for fixed or removable bridgework, or as a freestanding single tooth replacement.	Intended for surgical implantation in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary attachment for fixed or removable bridgework, or as a freestanding single tooth replacement.	Intended to provide support for prosthetic constructions for fully and partially edentulous arches using one or two stage surgical procedures.
Indication	Immediate Load	Immediate Load	Immediate Load
General Design	Threaded, root form implant	Threaded, root form implant	Threaded, root form implant
Placement Method	Two or single stage surgery	Two or single stage surgery	Two or single stage surgery
Material	Titanium alloy	Titanium alloy	Commercially pure titanium
Implant Body Type	Threaded body with micro-threads at the collar section	Threaded body with smooth collar	Threaded body with micro-threads at the collar section
Body Diameter	3.7mm, 4.7mm, 5.7 mm	3.7mm, 4.7mm, 6.0mm	3.5, 4.0 mm
Lengths	8mm – 16mm	8mm – 16mm	8mm – 19 mm
Platform Diameter	ScrewPlant: 3.7, 4.7, 5.7mm Legacy: 3.5, 4.5, 5.7mm	3.5, 4.5, 5.7mm	3.5, 4.0, 4.5, 5.0mm
Implant Surface	Roughened (HA blasted) or Roughened (HA blasted) and	HA coated./Roughened or Roughened – HA Blasted	Micro-roughened surface

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	plasma HA coated		
Packaging	Inner sleeve to suspend the implant assembled with a plastic carrier or titanium fixture mount inside an outer vial sealed with a cap. Packaging may include surgical cover screw, extender, and coping.	Double vial system. The implant/fixture-mount assembly is suspended and snaps inside the inner vial. The packaging also offers a surgical cover screw.	Implants are packaged with a carrier.
Sterilization	Gamma irradiation	Gamma irradiation	Unknown

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Table 2: Two-Stage Implants – RePlant

Technological Characteristics	RePlant Implants	Predicate Device: Tapered Screw-Vent (K013227)
Intended Use	Intended for surgical implantation in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary attachment for fixed or removable bridgework, or as a freestanding single tooth replacement.	Intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices for single or multiple unit restorations in splinted or non-splinted applications.
Indication	Immediate Load	Immediate Load
General Design	Threaded, root form implant	Threaded, root form implant
Placement Method	Two or single stage surgery	Two or single stage surgery
Material	Titanium alloy	CP4 Titanium
Implant Body Type	Threaded body with micro-threads at the collar section	Threaded body with groves at the collar section
Body Diameter	3.5mm, 4.3mm, 5.0mm, 6.0mm	3.5mm, 4.3mm, 5.0mm, 6.0mm
Lengths	8mm – 16mm	8mm – 16mm
Platform Diameter	3.5mm, 4.3mm, 5.0mm, 6.0mm	3.5mm, 4.3mm, 5.0mm, 6.0mm
Implant Surface	Roughened (HA blasted)	Roughened surface
Packaging	Inner sleeve to suspend the implant assembled with a plastic carrier or titanium fixture mount inside an outer vial sealed with a cap. Packaging may include surgical cover screw, extender, and coping.	Outer vial and cap
Sterilization	Gamma irradiation	Gamma irradiation

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Table 3: One-Stage Implants

Technological Characteristics	ScrewPlus Implants	ScrewIndirect Implants	Predicate Device: Advent and SwissPlus Dental Implant Systems (K011245)	Predicate Device: Astra-Tech Imp.Immediate Function (K041492)
Intended Use	Intended for surgical implantation in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary attachment for fixed or removable bridgework, or as a freestanding single tooth replacement.	Intended for surgical implantation in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary attachment for fixed or removable bridgework.	Intended for surgical implantation in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary attachment for fixed or removable bridgework, or as a freestanding single tooth replacement.	Intended to provide support for prosthetic constructions for fully and partially edentulous arches using one or two stage surgical procedures.
Indication	Immediate Load	Immediate Load	Immediate Load	Immediate Load
General Design	Threaded, root form implant	Threaded, root form implant	Threaded, root form implant	Threaded, root form implant
Placement Method	Single stage surgery	Single stage surgery	Single stage surgery	Two or single stage surgery
Material	Titanium alloy	Titanium alloy	Titanium alloy	Commercially pure titanium
Implant Body Type	Threaded body with smooth collar	Threaded body with smooth collar	Threaded body with smooth collar	Threaded body with micro-threads at the

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				collar section
Body Diameter	3.7, 4.7, and 5.7mm	3.7, 4.7, and 5.7mm	3.7, 4.7, and 6.0mm	3.5, and 4.0mm
Lengths	8mm – 16mm	8mm – 16mm	8mm – 16mm	8mm – 19 mm
Platform Diameter	3.7, 4.7, 5.7, and 6.5mm	5.0mm	4.5 and 5.7mm	3.5, 4.0, 4.5, 5.0mm
Implant Surface	Roughened – HA Blasted	Roughened – HA Blasted	HA coated /Roughened or Roughened – HA Blasted	Micro-roughened surface
Packaging	Inner sleeve to suspend the implant/fixture-mount assembly inside an outer vial sealed with a cap. Packaging also includes surgical cover screw, extender, and temporary coping	Inner sleeve to suspend the implant/carrier assembly inside an outer vial sealed with a cap. Packaging also includes, extender, and temporary coping	Implants are packaged with a carrier in a double vial system. The packaging also offers a surgical cover screw and an extender.	Implants are packaged with a carrier.
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation	Unknown

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Table 4: One-Piece Implants

Technological Characteristics	ScrewDirect Implants	ScrewRedirect Implants	Predicate Device: Replace One-Piece Implant (K023952)	Predicate Device: Lifecore PrimaSolo One-Piece Implant System (K050506)
Intended Use	Intended for single stage surgical procedures and cemented restorations.	Intended for single stage surgical procedures and cemented restorations.	Intended for single stage surgical procedure and cemented restorations.	Intended for single stage surgical procedures and cement restorations.
Indication	Immediate Load	Immediate Load	Immediate Load	Immediate Load
General Design	Threaded, root form implant	Threaded, root form implant	Threaded, root form implant	Threaded, root form implant
Placement Method	Single stage surgery	Single stage surgery	Single stage surgery	Single stage surgery
Material	Titanium alloy	Titanium alloy	CPe titanium	Titanium alloy
Implant Body Type	Tapered threaded body with an integrated abutment	Tapered threaded body with an integrated angled abutment	Tapered threaded body with an integrated abutment	Tapered threaded body with an integrated abutment
Body Diameter	3.0, 3.7, 4.7, and 5.7mm	3.7, 4.7, and 5.7mm	3.5, 4.3, and 5.0mm	3.0, 3.5, 4.1, and 5.0mm
Lengths	10, 13, and 16mm	13 and 16mm	10, 13, and 16mm	10mm – 15 mm
Implant Surface	Roughened – HA Blasted	Roughened – HA Blasted	HA coated and roughened surface	Micro-roughened surface
Packaging	Inner sleeve to suspend the implant/carrier assembly inside an outer vial sealed with a cap. Packaging also	Inner sleeve to suspend the implant/carrier assembly inside an outer vial sealed	Unknown	Unknown

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	includes a temporary coping	with a cap.		
Sterilization	Gamma irradiation	Gamma irradiation	Unknown	Unknown

5. Conclusion:

Based on the comparison analysis, the identical intended use, comparable technological characteristics, similar general design features, the Spectra System is substantially equivalent to the predicate devices. The seven implants of the Spectra-System and their related components are safe and effective for its intended use.

1 (i) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the Premarket notification are truthful and accurate and that no material fact has been omitted.

A Truthful and Accurate Statement is included in **Section 3.0,** signed by Dr. Gerald A. Niznick, the owner of Implant Direct LLC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2006

Ms. Patty McMahon
Vice President
Implant Direct, LLC
27030 Malibu Hills Road
Calabasas Hills, California 91301

Re: K061319
Trade/Device Name: Spectra Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: July 28, 2006
Received: July 31, 2006

Dear Ms. McMahon:

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.

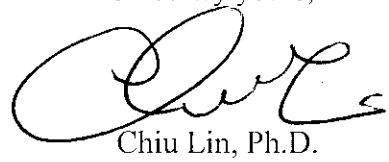
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K061319

Device Name: Spectra Dental Implant System

Indications for Use:

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The ScrewDirect 3.0mm implant is indicated for:

1. An artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
2. Multiple tooth replacements or denture stabilization.

The Screw Redirect implant is intended for support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of the partially edentulous maxillary jaw. It is indicated for immediate functional loading when four or more implants are splinted together in the endentulous upper or lower jaw.

The Screw Indirect implant is indicated for the support and retention of bar overdentures or as a terminal or intermediary attachment for screw-retained fixed bridgework. It is indicated for immediate functional loading when four or more implants are splinted together in the edentulous upper or lower jaw. This implant model is not indicated for use with abutments, only with a 2mm extender.

Prescription Use __√__ (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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Beltz DDS for W. Susan Runner

(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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