K960371

Exhibit 3

510(k) SUMMARY

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SUBMITTED BY

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CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Endosseous Implant
Common/Usual Name:	Dental Implant
Proprietary Names:	INTERPORE Threaded Implant (Wide Diameter)

PREDICATE DEVICES

Nobelpharma Threaded Implants
Implant Innovations, Inc. (3i) Threaded Implants
Lifecore Threaded Implants

DEVICE DESCRIPTION

The INTERPORE Self-Tapping Threaded Implant is a commercially pure titanium, machined, endosseous threaded implant with an external hex configuration on the top of the implant. The outer surface of the implant is externally threaded. The external threads originate at the inferior edge of the machined coronal collar of the implant and continue to the apical end of the implant. The apical end of the implant contains flutes which act as cutting edges to aid installation of the implant during the self-tapping procedure. The inner diameter of the implant is internally threaded with 2.5 mm threads designed for acceptance of a placement screw, a hex cover screw, a healing abutment, and a retaining screw. The latter device affixes the prosthetic appliance to the implant.

The incorporation of the external hexagonal projection is intended to provide an attachment system which minimizes crown rotation in single tooth applications. It is designed to mechanically interface with a female hexagonal configuration on the mating prosthesis such that, when the retaining screw is tightened into place, the crown will not be allowed to rotate.

It also provides a wide variety of options with regard to the types of abutments that can be used for attachment of prostheses.

INDICATIONS FOR USE

The INTERPORE Self-Tapping Threaded Implant is indicated for oral reconstruction in the totally edentulous mandible or maxilla, in large edentulous spans, for bilateral and unilateral free-ends and in restoration of single tooth edentulous spaces. It is designed to become an osteointegrated prosthesis allowing the attachment of removable and fixed partial or complete prosthodontic appliances. The external hexagonal projection is intended to provide an attachment system which minimizes crown rotation in single tooth applications.

PRINCIPLES OF OPERATION

Oral reconstruction using the INTERPORE Self-Tapping Threaded Implant is a two phase procedure. In Phase I, the implant cylinder is surgically implanted in the residual ridge of the mandible or maxilla. Internally irrigated, precision drills are used to prepare the implant site. The INTERPORE Self-Tapping Threaded Implant is designed to be either self-tapped into place or the implant site may be pre-tapped using the Hand Bone Tap and Mount Driver or Ratchet Wrench. The implant is then properly seated, and the titanium Hex Cover Screw is affixed to seal the implant. Soft tissue is sutured into place to cover the implant and the implant is allowed to heal (osteointegrate) for approximately three to four months. During the healing period, the implant is not loaded, thus allowing the implant to heal in a stress-free environment.

After healing, Phase II procedures are initiated. The soft tissue over the implant is reopened, and the titanium Hex Cover Screw is removed. It is replaced with the Hex Healing Abutment, an abutment of appropriate height and diameter, which allows the gingiva to heal to the desired contour. Approximately two weeks later, the Hex Healing Abutment is removed and an impression of the top of the implant is made using an appropriate Hex Impression Coping which is mounted on the implant. Once the impression is made, the impression coping is removed and the Hex Healing Abutment is replaced onto the implant until the construction of the prosthodontic appliance has been completed by the dental laboratory. Final attachment of the prosthesis involves removing the Hex Healing Abutment, seating the prosthesis and tightening the titanium retaining screw.

CONTRAINDICATIONS

Contraindications customary to oral surgery should be observed. These include, but are not limited to, uncontrolled parafunctional habits, significant vascular impairment to the implant site, metabolic bone disease, clotting disorders, current treatment with therapeutic agents which may have an effect on the surgical site, the surrounding tissue or normal biological healing responses (i.e., drug therapy, radiation therapy, chronic steroid treatment,

anticoagulant therapy) and uncontrolled diabetes or other metabolic or systemic disorders which affect bone or wound healing.

The implant must not be used in patients where ridge dimensions are insufficient to accommodate proper implant placement.

Implants should not be used in patients who present with an active intraoral infection at the time of placement.

COMPLICATIONS

The following complications have been reported in association with surgical procedures employing endosteal implants: failure to osteointegrate, loosening and loss of implant, soft tissue irritation due to insufficient width of attached gingiva, infection, early loss of implant due to inability to remove healing screw at reopening, implant loosening and fracture associated with coronal bone loss with apical retention.

MATERIALS OF CONSTRUCTION

Implant Cylinder	Commercially pure titanium conforming to ASTM F-67, Unalloyed Titanium for Surgical Implant Applications.
Hex Cover Screw	Titanium alloy TI-6AL-4V ELI conforming to ASTM F-136, Wrought Titanium 6AL-4V ELI Alloy for Surgical Implant Applications.
Healing Abutments	Titanium alloy TI-6AL-4V ELI conforming to ASTM F-136, Wrought Titanium 6AL-4V ELI Alloy for Surgical Implant Applications.
Impression Copings	Titanium alloy TI-6AL-4V ELI conforming to ASTM F-136, Wrought Titanium 6AL-4V ELI Alloy for Surgical Implant Applications.
Implant Analogs	Titanium alloy TI-6AL-4V ELI conforming to ASTM F-136, Wrought Titanium 6AL-4V ELI Alloy for Surgical Implant Applications.

Titanium Prosthetic Components	Commercially pure titanium conforming to ASTM F-67, Unalloyed Titanium for Surgical Implant Applications. Titanium alloy TI-6AL-4V ELI conforming to ASTM F-136, Wrought Titanium 6AL-4V ELI Alloy for Surgical Implant Applications.
Gold Prosthetic Components	Ceramicor, Everlast, or equivalent gold alloy with the following composition: 60% Gold, 20% Platinum, 20% Palladium
Castable Plastic Components	Delrin Resin #500, Manufactured by DuPont.
Paralleling Pin	Commercially pure titanium conforming to ASTM F-67, Unalloyed Titanium for Surgical Implant Applications. Titanium alloy TI-6AL-4V ELI conforming to ASTM F-136, Wrought Titanium 6AL-4V ELI Alloy for Surgical Implant Applications.
Thread Taps	Commercially pure titanium conforming to ASTM F-67, Unalloyed Titanium for Surgical Implant Applications. Titanium alloy TI-6AL-4V ELI conforming to ASTM F-136, Wrought Titanium 6AL-4V ELI Alloy for Surgical Implant Applications.
Spade Drills	17-4PH Stainless Steel (UNS-S17400) conforming to ASTM A-564, Hot-Rolled and Cold-Finished Age-Hardening Stainless and Heat-Resisting Steel Bars and Shapes.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The design, material, configurations, method of sterilization and other technological characteristics are similar to currently marketed predicate devices.

NONCLINICAL TEST CONCLUSIONS

Static testing was performed on the INTERPORE Threaded Implant and compared with existing mechanical test data for the Branemark 3.75 mm Threaded Implant. Results showed that the INTERPORE Threaded Implant was significantly stronger than the Branemark implant.