DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 27, 2015

Dental Evolutions Inc.
c/o Ms. Priscilla Chung
LK Consulting Group USA, Inc.
2651 East Chapman Avenue Suite 110
Fullerton, California 92831

Re: K150040
Trade/Device Name: Implanova®
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 23, 2015
Received: July 28, 2015

Dear Ms. Chung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150040

Device Name

Implanova®

Indications for Use *(Describe)*

The Implanova® Bone Level implants are intended for endosseous implantation in the mandible and maxilla for use as an artificial root structure. These root form implants can be used to replace single or multiple missing teeth and/or to support a fixed or removable prosthesis in partially or completely edentulous upper and lower dental arches. All devices in the Implanova® Bone Level system, including implant fixtures, abutments, healing caps, cover screws, and retention screws are intended for use by prescription only. Implanova® Bone Level implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Implanova® All-in-One3.0mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The Implanova® All-in-One 3.0mm implant must be splinted if two or more are used adjacent to each other. Implanova® All-in-One 3.0mm implant are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

All Implanova® Bone Level implant fixtures are compatible with the straight type restorative components listed in the table below, including straight type abutments, straight type abutment screws and straight type temporary abutments that are intended to be on Astra Tech's OsseoSpeed™ TX 3.5S and OsseoSpeed™ TX 4.0S implant fixtures.

Implanova®Bone Level to Astra Tech Compatibility List				
Component Type	Part #	Device Name	Manufacturer	Compatible Implanova® Bone Level Fixtures
Healing Abutment	22851	TempDesign™3.5/4.0	Astra Tech	All Bone Level Implants
Healing Abutment	22853	TempDesign™3.5/4.0 NI	Astra Tech	All Bone Level Implants
Healing Abutment	24281	Temporary Abutment 3.5/4.0	Astra Tech	AllBone Level Implants
Healing Abutment	24280	Temporary Abutment 3.5/4.0 NI	Astra Tech	AllBone Level Implants
Abutment Screw	24449	Abutment Screw Design 3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24910 - 24916	Direct Abutment™3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24917 - 24923	Direct Abutment API™3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24893 - 24898	20° UniAbutment 3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24899 - 24904	45° UniAbutment 3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24905 - 24909	Ball Abutment 3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24268 - 24272	Locator™ Abutment 3.5/4.0	Astra Tech	AllBone Level Implants

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 08/24/2015

1. **Applicant / Submitter**

Dental Evolutions Inc.
9100 Wilshire Blvd. Suite W448
Beverly Hills, CA 90212

Phone. 310.273.2819
Fax. 310. 273.3319

2. **Submission Correspondent**

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave. Ste 110, Fullerton CA 92831
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. **Device**

- Trade Name: Implanova®
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant
- Product Code: DZE, NHA
- Classification regulation: 21CFR872.3640 Class II

4. **Predicate Device:**

- Primary Predicate Device
  - BioHorizons Tapered Internal Plus Implants by BioHorizons Implant Systems, Inc. (K121787)
- Reference Predicate Devices
  - BioHorizons Internal Implants by BioHorizons Implant Systems, Inc. (K073268)
  - U fit Dental Implant System by T Strong Inc. (K132956)
  - Zimmer One-Piece Implant System by Zimmer Dental Inc. (K052997)
  - NobelDirect 3.0 by Nobel Biocare USA LLC (K070857)

- Astra Tech Implant System, New Components , Angled TiDesign Abutment by Astra Tech AB (K101005, K072624)
- NC Closure Screws, Straumann Closure Screws by Straumann USA (K130808, K071585)
- Straumann Healing Abutments, RC Closure Screws, RC Healing Abutments by Straumann USA(K062129, K130808, K070478, K960634)
- OsseoSpeed™ Profile System by Astra Tech AB (K080156)

5. Description:

All bone fixtures within Inplanova® system are endosseous dental implants and are available in Bone Level and All-In-One implants types. Fixtures are available in the following sizes.

• IMPLANOVA® BONE LEVEL IMPLANTS
Narrow Medium: 3.5mm Diameter x 10mm Length
Narrow Long: 3.5mm Diameter x 12mm Length
Narrow XLong (Extra Long): 3.5mm Diameter x 14mm Length

Standard Short: 4.5mm Diameter x 8mm Length
Standard Medium: 4.5mm Diameter x 10mm Length
Standard Long: 4.5mm Diameter x 12mm Length
Standard XLong: 4.5mm Diameter x 14mm Length

Wide Short: 5.5mm Diameter x 8mm Length
Wide Medium: 5.5mm Diameter x 10mm Length
Wide Long: 5.5mm Diameter x 12mm Length

• IMPLANOVA® ALL-IN-ONE IMPLANTS
Slender Medium: 3.0mm Diameter x 10mm Length
Slender Long: 3.0mm Diameter x 12mm Length
Slender XLong (Extra Long): 3.0mm Diameter x 14mm Length

The material constituents of the all implant fixtures within the Implanova® system is Grade 23 Titanium Alloy per ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vnadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*In order to promote osseointegration, a variable portion of the implant surface, depending on the implant's overall length, is surface treated and passivated per ASTM F86 standard.

Abutments for bone level implants are utilized for cement retained restoration. Bone level abutments are available in straight and angled types as well as platform sizes ranging from 4.2mm to 6.5mm. All bone level angled abutments will utilize their respective abutment screw for installation. The material constituents of all Implanova® abutments is grade 23titanium alloy per ASTM F136 *Standard Specification for Wrought Titanium-*

6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

Implanova® Bone Level Abutments offer the following models.

• IMPLANOVA® BONE LEVEL ABUTMENTS
Narrow Platform – Straight: 4.2 mm Platform Diameter x 5.7 mm Post Height
Narrow Platform – 15 Degrees: 4.2 mm Platform Diameter x 7.3 mm Post Height
Narrow Platform – 20 Degrees: 4.2 mm Platform Diameter x 7.3 mm Post Height

Standard Platform – Straight: 4.8 mm Platform Diameter x 5.7 mm Post Height
StandardPlatform – 15 Degrees: 4.8 mm Platform Diameter x 7.3 mm Post Height
StandardPlatform – 20 Degrees: 4.8 mm Platform Diameter x 7.3 mm Post Height

Wide Platform – Straight: 6.5 mm Platform Diameter x 5.7 mm Post Height
WidePlatform – 15 Degrees: 6.5 mm Platform Diameter x 7.3 mm Post Height
WidePlatform – 20 Degrees: 6.5 mm Platform Diameter x 7.3 mm Post Height

The system also offers Healing Caps and Cover Screws.

OsseoSpeed™ Profile System (K080156) is identified as a referenced predicated as the Implanova Bone Level Implant are compatible with the 3rd party straight abutment listed in the Indications for Use and cleared in K080156.

6. Indications for use:

The Implanova® Bone Level implants are intended for endosseous implantation in the mandible and maxilla for use as an artificial root structure. These root form implants can be used to replace single or multiple missing teeth and/or to support a fixed or removable prosthesis in partially or completely edentulous upper and lower dental arches. All devices in the Implanova® Bone Level system, including implant fixtures, abutments, healing caps, cover screws, and retention screws are intended for use by prescription only. Implanova® Bone Level implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Implanova® All-in-One3.0mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The Implanova® All-in-One 3.0mm implant must be splinted if two or more are used adjacent to each other. Implanova® All-in-One 3.0mm implant are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

All Implanova® Bone Level implant fixtures are compatible with the straight type restorative components listed in the table below, including straight type abutments,

straight type abutment screws and straight type temporary abutments that are intended to be on Astra Tech's OsseoSpeed™ TX 3.5S and OsseoSpeed™ TX 4.0S implant fixtures.

Implanova®Bone Level to Astra Tech Compatibility List				
Component Type	Part #	Device Name	Manufacturer	Compatible Implanova® Bone Level Fixtures
Healing Abutment	22851	TempDesign™3.5/4.0	Astra Tech	All Bone Level Implants
Healing Abutment	22853	TempDesign™3.5/4.0 NI	Astra Tech	All Bone Level Implants
Healing Abutment	24281	Temporary Abutment 3.5/4.0	Astra Tech	AllBone Level Implants
Healing Abutment	24280	Temporary Abutment 3.5/4.0 NI	Astra Tech	AllBone Level Implants
Abutment Screw	24449	Abutment Screw Design 3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24910 - 24916	Direct Abutment™3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24917 - 24923	Direct Abutment API™3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24893 - 24898	20° UniAbutment 3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24899 - 24904	45° UniAbutment 3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24905 - 24909	Ball Abutment 3.5/4.0	Astra Tech	AllBone Level Implants
Abutment	24268 - 24272	Locator™ Abutment 3.5/4.0	Astra Tech	AllBone Level Implants

7. Basis for Substantial Equivalence

Implanova® is substantially equivalent to previously marketed devices. Overall, the Implanova® has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same material and the surface treatment.
- has similar size range

The subject device is similar to the predicate devices based on the intended use, the principle of operations, the materials, the surface treatment, the size range and the technological characteristics. The external design of the subject device is slightly different from the predicate devices; however, the performance testing provided in this 510K submission supports that the subject device is substantially equivalent to the predicate devices.

The detailed comparison chart is provided on the following pages.

Comparative Table for Bone Level Implant

	Subject Device	Primary Predicate Device	Reference Predicate Device1	Reference Predicate Device2
510(K) Number	-	K121787	K073268	K132956
Device Name	Implanova® Bone Level Implant	BioHorizons Tapered Internal Plus Implants	BioHorizons Internal Implants	U fit Dental Implant System
Manufacturer	Dental Evolutions Inc.	BioHorizons Implant Systems, Inc.	BioHorizons Implant Systems, Inc.	T Strong Inc.
Connection Type	Internal Hexagon	Internal Hexagon	Internal Hexagon	Internal Hexagon
Size Range	Diameter: 3.5mm, 4.5mm, 5.5mm Length: 8mm (excluding 3.5mm diameter), 10mm, 12mm, 14mm (excluding 5.5mm diameter)	Diameter: 3.8mm, 4.6mm, 5.8mm Length: 7.5mm (excluding 3.8mm diameter), 9mm, 10.5mm, 12mm, 15mm	Diameter: 3.5mm, 4.0mm, 5.0mm, 6.0mm Length: 9mm, 10.5mm, 12mm, 15mm	Diameter: 3.8mm, 3.9mm, 4.0mm, 4.2mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 7.0mm Length: 7mm, 8.5mm, 10mm, 11.5mm, 13mm, 14.5mm
Indications for Use	The Implanova® Bone Level implants are intended for endosseous implantation in the mandible and maxilla for use as an artificial root structure. These root form implants can be used to replace single or multiple missing teeth and/or to support a fixed or removable prosthesis in partially or completely edentulous upper and lower dental arches. All devices in the Implanova® Bone Level system, including implant fixtures, abutments, healing caps, cover screws, and retention screws are intended for use by prescription only. Implanova® Bone Level implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	BioHorizons Tapered Internal Plus Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridge work and dental retention. Theimplants may be restored immediately (1) with atemporaryprosthesis that is not in functional occlusion or (2) when splinted together for multipletooth replacement or when stabilized with an overdenture supported by multiple implants.	BioHorizons Internal Implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. BioHorizons Internal Implants may be restored immediately (1) with a temporary prosthesis that is not in functional occlusion, or (2) when splinted together for multiple tooth replacement, or when stabilized with an overdenture supported by multiple implants.	The U fit Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The U fit Dental Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

	Implanova® All-in-One 3.0mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The Implanova® All-in-One 3.0mm implant must be splinted if two or more are used adjacent to each other. Implanova® All-in-One 3.0mm implant are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. All Implanova® Bone Level implant fixtures are compatible with the straight type restorative components listed in the table below, including straight type abutments, straight type abutment screws and straight type temporary abutments that are intended to be on Astra Tech's OsseoSpeed™ TX 3.5S and OsseoSpeed™ TX 4.0S implant fixtures.			
Design Characteristics	- Self-tapping - Bone-level type implant - Micro-threaded implant collar - Tapered implant body	- Self-tapping - Bone-level type implant - Laser-Lok® microchannels implant collar - Tapered implant body	- Self-tapping - Bone-level type implant - Laser-Lok® microchannels implant collar - Tapered implant body	- Self-tapping - Bone-level type implant - Micro-threaded implant collar - Tapered implant body
Material Composition	Titanium Alloy grade 23 (Ti6Al4V ELI)	Titanium Alloy grade 23 (Ti6Al4V ELI)	Titanium Alloy grade 23 (Ti6Al4V ELI)	Titanium Alloy grade 23 (Ti6Al4V ELI)
Surface Treatment	- Resorbable Blast Texture Media (calcium phosphate)	- Resorbable Blast Texture Media (calcium phosphate)	- Resorbable Blast Texture Media (calcium phosphate)	- Resorbable Blast Texture Media

	- Partial surface treatment			
Sterile	Yes	Yes	Yes	Yes
Sterilization Method	Gamma Radiation	Gamma Radiation	Gamma Radiation	Gamma Radiation
Differences in Technological Characteristics (vs. subject device)	(Subject Device)	A notable difference, when compared to the subject device, is the Laser-Lok® micro-machined grooves on this predicate device and the micro threads on the cervical area of subject device. The Laser-Lok® feature on the predicate device and the microthreads on the subject device are functionally identical. They do not render the device NSE because the osteocytes cannot differentiate the microscopic differences in topography in osseointegration. Another notable difference when compared to the subject device, are the length of the flutes. Although the subject device exhibit longer flute lengths, flutes on both BioHorizon *Tapered Internal Plus* and the Implanova subject devices are designed for self-tapping (self-threading) and are functionally similar. This difference does not make the subject device NSE because more tapping edges simply ease the tapping processes but functions the same. Another notable difference between subject device and the predicate is the twist direction of the vertical flutes. The subject	A notable difference, when compared to the subject device, is the Laser-Lok® micro-machined grooves on this predicate device and the micro threads on the cervical area of subject device. They do not render the device NSE because the osteocytes cannot differentiate the microscopic differences in topography in osseointegration. Another notable difference when compared to the subject device, are the length of the flutes. Although the subject device exhibit longer flute lengths, flutes on both BioHorizon *Internal Implants* and the Implanova subject devices are designed for self-tapping (self-threading) and are functionally similar. This difference does not make the subject device NSE because more tapping edges simply ease the tapping processes but functions the same. Another notable difference between subject device and the predicate is the twist direction of the vertical flutes. The subject device's vertical flute is a very minor left hand twist (18mm pitch). Majority of implants in	A notable difference between subject device and the predicate is the twist direction of the vertical flutes. The subject device's vertical flute is a very minor left hand twist (18mm pitch), while the predicate device possesses a slight right hand twist. The function of flutes in subject andpredicate device is to provide cutting edges for the tapping feature of the fixture as well as to provide clearances for the consolidation of swarf material (bone debris). The minor left hand helical twist of the subject device only slightly increases the sharpness of the edges of the implant's tapping features and passively guides the swarf materials to consolidate in the provided flute clearances. Thus, the slight helical twist of the subject device should not render the device NSE. Another notable difference between subject device and the predicate is the partial surface treatment of the subject device. While the surfaces of the predicate devices are modified throughout the implant body, the subject device is

		device's vertical flute is a very minor left hand twist (18mm pitch). Majority of implants in market including the predicate device have a straight vertical flute. The function of flutes in subject andpredicate device is to provide cutting edges for the tapping feature of the fixture. The minor left hand helical twist of the subject device only slightly increases the sharpness of the edges of the implant's tapping features and passively guides the swarf materials to consolidate in the provided flute clearances. Thus, the slight helical twist of the subject device should not render the device NSE. Another notable difference between subject device and the predicate is the partial surface treatment of the subject device. While the surfaces of the BioHorizons Tapered Internal Plus implants are modified throughout the implant body, the subject device is modified throughout the body except the apical 5 mm. The subject fixture's untreated apical area maintains the sharpness of the tapping edges for cutting (tapping) of the bone. Since surface treatment is not a requirement for osseointegration, this difference does not make the subject device NSE. (All original Branemark implants were machine	market including the predicate device have a straight vertical flute. The function of flutes in subject andpredicate device is to provide cutting edges for the tapping feature of the fixture. The minor left hand helical twist of the subject device only slightly increases the sharpness of the edges of the implant's tapping features and passively guides the swarf materials to consolidate in the provided flute clearances. Thus, the slight helical twist of the subject device should not render the device NSE. Another notable difference between subject device and the predicate is the partial surface treatment of the subject device. While the surfaces of the predicate devices are modified throughout the implant body, the subject device is modified throughout the body except the apical 5 mm. The subject fixture's untreated apical area maintains the sharpness of the tapping edges for cutting (tapping) of the bone. Since surface treatment is not a requirement for osseointegration, this difference does not make the subject device NSE. (All original Branemark implants were machine finished and did not have any surface treatments) Despite these differences in	modified throughout the body except the apical 5 mm. Both treated areas identically functions in order to increase surface area for osseointegration. The subject fixture's untreated apical area maintains the sharpness of the tapping edges for cutting (tapping) of the bone. Since surface treatment is not a requirement for osseointegration, this difference does not make the subject device NSE. (All original Branemark implants were machine finished and did not have any surface treatments) Despite these differences in design, the fatiguetest result of the subject device supports that the subject device is substantially equivalent to the predicate devices.

		finished and did not have any surface treatments) Despite these differences in design, the fatiguetest result of the subject device supports that the subject device is substantially equivalent to the predicate devices.	design, the fatiguetest result of the subject device supports that the subject device is substantially equivalent to the predicate devices.	

Comparative Table for All-in-One Implant

	Subject Device	Reference Predicate Device	Reference Predicate Device
510(K) Number	-	K052997	K070857
Device Name	Implanova® All-In-One Implant	Zimmer One-Piece Implant System	NobelDirect 3.0
Manufacturer	Dental Evolutions Inc.	Zimmer Dental Inc.	Nobel Biocare USA LLC
Connection Type	N/A	N/A	N/A
Design & Size Range	Diameter: 3.0mm Length: 10mm, 12mm, 14mm	Diameter: 3.0mm Length: 10.0mm, 11.5mm, 13.0mm, 16.0mm	Diameter: 3.0mm Length: 13.0mm, 15.0mm
Intended Use	The Implanova® Bone Level implants are intended for endosseous implantation in the mandible and maxilla for use as an artificial root structure. These root form implants can be used to replace single or multiple missing teeth and/or to support a fixed or removable prosthesis in partially or completely edentulous upper and lower dental arches. All devices in the Implanova® Bone Level system, including implant fixtures, abutments, healing caps, cover screws, and retention screws are intended for use by prescription only. Implanova® Bone Level implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implanova® All-in-One 3.0mm implants	Zimmer® One-Piece 3.7mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of partially edentulous jaws. Zimmer® One-Piece 3.7mm implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. The Zimmer® 3.7mm One-Piece implant may be immediately restored with a temporary prosthesis that is not in functional occlusion. Zimmer® One-Piece 3.0mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The Zimmer® One-Piece 3.0mm implant must be splinted if two or more are used adjacent to	The Nobel Direct 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices such as artificial teeth, in order to restore chewing function in partially edentulous patients. The Nobel Direct 3.0 Implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied. Mandible central and lateral incisors must be splinted if using two or more 3.0mm implants adjacent to one another.

	are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The Implanova® All-in-One 3.0mm implant must be splinted if two or more are used adjacent to each other. Implanova® All-in-One 3.0mm implant are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. All Implanova® Bone Level implant fixtures are compatible with the straight type restorative components listed in the table below, including straight type abutments, straight type abutment screws and straight type temporary abutments that are intended to be on Astra Tech's OsseoSpeed™ TX 3.5S and OsseoSpeed™ TX 4.0S implant fixtures.	each other. The Zimmer® One-Piece 3.0mm implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.	
Design Characteristics	- Self-tapping - Tissue-level type implant - Micro-threaded implant collar - Tapered implant body	- Self-tapping - Tissue-level type implant	- Self-tapping - Tissue-level type implant - Full length tapping
Material Composition	Titanium Alloy grade 23 (Ti6Al4V ELI)	Titanium Alloy grade 23 (Ti6Al4V ELI)	CP Titanium grade 4
Surface Treatment	- Resorbable Blast Texture Media (calcium phosphate) - Partial surface treatment	- Hydroxyapatite (calcium phosphate group) blast media	- TiUnite (phosphate enriched titanium oxide) surface treatment
Sterile	Yes	Yes	Yes
Sterilization Method	Gamma Radiation	Gamma Radiation	Gamma Radiation
Differences in Technological Characteristics (vs. subject device)	(Subject Device)	A notable difference, when compared to the subject device, is the lack of microthreads. Microthreads on the subject device will only slightly increase the surface area of the bone-implant contact. The very minute topographic	A notable difference, when compared to the subject device, is the lack of microthreads. Microthreads on the subject device will only slightly increase the surface area of the bone-implant contact. The very minute topographic

		features and small increase in surface area on the subject device creates an insignificant deviation from the predicate design, thus does not render the subject device NSE. Another notable difference when compared to the subject device, are the length of the flutes. Although the subject device exhibit longer flute lengths, flutes on both predicate device and the Implanova subject devices are designed for self-tapping (self-threading) and are functionally similar. This difference does not make the subject device NSE because more tapping edges simply ease the tapping processes but functions the same. Another notable difference between subject device and the predicate is the twist direction of the vertical flutes. The subject device's vertical flute is a very minor left hand twist (18mm pitch). Majority of implants in market including the predicate device have a straight vertical flute. The function of flutes in subject And predicate device is to provide cutting edges for the tapping feature of the fixture as well as to provide clearances for the consolidation of swarf material (bone debris). The minor left hand helical twist of the subject device only slightly increases the sharpness of the edges of the implant's tapping features and passively guides the swarf materials to consolidate in the provided flute clearances. Thus, the slight helical twist of the subject device should not render the device NSE. Another notable difference between subject device and the predicate is the partial surface treatment of the subject device. While the surfaces of the predicate devices are modified throughout the implant body, the subject device	features and small increase in surface area on the subject device creates an insignificant deviation from the predicate design, thus does not render the subject device NSE. Another notable difference when compared to the subject device, are the length of the flutes. Although the subject device exhibit longer flute lengths, flutes on both predicate device and the Implanova subject devices are designed for self-tapping (self-threading) and are functionally similar. This difference does not make the subject device NSE because more tapping edges simply ease the tapping processes but functions the same. Another notable difference between subject device and the predicate is the twist direction of the vertical flutes. The subject device's vertical flute is a very minor left hand twist (18mm pitch). Majority of implants in market including the predicate device have a straight vertical flute. The function of flutes in subject And predicate device is to provide cutting edges for the tapping feature of the fixture as well as to provide clearances for the consolidation of swarf material (bone debris). The minor left hand helical twist of the subject device only slightly increases the sharpness of the edges of the implant's tapping features and passively guides the swarf materials to consolidate in the provided flute clearances. Thus, the slight helical twist of the subject device should not render the device NSE. Another notable difference between subject device and the predicate is the partial surface treatment of the subject device. While the surfaces of the predicate device are modified throughout the implant body, the subject

		is modified throughout the body except the apical 5 mm. The subject fixture's untreated apical area maintains the sharpness of the tapping edges for cutting (tapping) of the bone. Since surface treatment is not a requirement for osseointegration, this difference does not make the subject device NSE. (All original Branemark implants were machine finished and did not have any surface treatments)	device is modified throughout the body except the apical 5 mm. The subject fixture's untreated apical area maintains the sharpness of the tapping edges for cutting (tapping) of the bone. Since surface treatment is not a requirement for osseointegration, this difference does not make the subject device NSE. (All original Branemark implants were machine finished and did not have any surface treatments). Although the material used in the surface modification of the subject device is not the same with the predicate device, the chemical analysis data provided in the section "7.8 Surface Treatment Method" of this submission" supports that the blast media used for the subject device does not alter surface chemical compositions.

Comparative Table for Bone Level Straight Abutment

	Subject Device	Predicate Device
510(K) Number	-	K101005, K072624
Device Name	Implanova® Bone Level Straight Abutments	Astra Tech Implant System, New Components
Manufacturer	Dental Evolutions Inc.	Astra Tech AB
Connection type	Screw Retained	Screw Retained
Design & Size Range	Platform Diameter: 4.2mm, 4.8mm, 6.5 mm Post Height: 5.7 mm Platform Height: 2 mm Thread Type: M1.6	Platform Diameter: 4.0mm, 5.0mm, 6.0mm Post Height: 5.0mm, 5.5mm Platform Height: 0.5mm, 1.0mm, 2.5mm, 4.0mm Thread Type: M1.6
Intended Use	Intended use is identical to the predicate device	Cement retained restoration
Design Characteristics	- Straight abutment - Non-indexed seating - Screws directly into implant assembly - Tapered abutment-to-crown cementing areas - .05" Hexagonal socket for carrying, seating and retrieval	- Straight abutment - Non-indexed seating - Screws directly into implant assembly - Tapered base for hermetic/bacterial seal with implant during assembly - Tapered abutment-to-crown cementing areas - .05" Hexagonal socket for carrying, seating and retrieval

Material Composition	Titanium Alloy grade 23 (Ti6Al4V ELI)	CP Titanium grade 4
Surface Treatment	No	No
Sterile	No	No
Sterilization Method	N/A	N/A
Differences in Technological Characteristics (vs. subject device)	(Subject Device)	There are no major design difference between this abutment and the Implanova subject device. Although the material composition of this device is Grade 4 Titanium while the subject device is Grade 23 Titanium, both materials used in the predicate and subject device are remarkably similar in performance, and both grade 4 and grade 23 titanium are commonly used for implantation.

Comparative Table for Bone Level Angled Abutment

	Subject Device	Predicate Device
510(K) Number	-	K101005, K072624
Device Name	Implanova® Angled Bone Level Abutment	Astra Tech Implant System, New Components Angled TiDesign Abutment
Manufacturer	Dental Evolutions Inc.	Astra Tech AB
Connection type	Screw Retained/ Hexagonal seating index	Screw Retained/ Hexagonal seating index
Design & Size Range	Platform Diameter: 4.2mm, 4.8mm, 6.5 mm Post Angle:15° and 20° Platform Height: 2 mm	Platform Diameter: 4.0 mm Post Angle:15° and 20° Platform Height: 2.4 mm
Intended Use	Intended use is identical to the predicate device	Cement retained restoration
Design Characteristics	- Angled abutment - Hexagonal seating index - Tapered base for hermetic/bacterial seal with implant during assembly - Tapered abutment-to-crown cementing areas	- Angled abutment - Hexagonal seating index - Tapered base for hermetic/bacterial seal with implant during assembly - Tapered abutment-to-crown cementing areas
Material Composition	Titanium Alloy grade 23 (Ti6Al4V ELI)	CP Titanium grade 4
Surface Treatment	No	No
Sterile	No	No
Sterilization Method	N/A	N/A
Differences in Technological Characteristics (vs. subject device)	(Subject Device)	There are no major design difference between this abutment and the Implanova subject device. Although the material composition of this device is Grade 4 Titanium while the subject device is Grade 23 Titanium, both materials used in the predicate and subject device are remarkably similar in performance, and both grade 4 and grade 23 titanium are commonly used for implantation.

8. Non-Clinical Testing

The following testing was performed and the test results supported that the subject device is substantially equivalent to the predicate devices and it is in conformance with the FDA guidance document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments.

- Fatigue Testing according to ISO 14801
- 3rdParty Compatibility
- Sterilization Validationaccording to ISO 11137-1, ISO 11137-2, ISO11737-1, ISO11737-2, ISO 17665-1 and ISO 17665-2
- Shelf-life Validation according to ASTM F1980, ISO 11607-1, ISO 11607-2, ASTM F88, and ASTM F 1929
- Cytotoxicity Testing according to ISO 10993-5
- SEM/EDS Chemical Surface Analysis

9. Conclusion

Based on the similarities, we conclude that the Implanova® system is substantially equivalent to its predicate devices.