DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 30, 2017

SpiralTech Superior Dental Implants
Daniel Rosenthal
Director of Sales and Marketing
875 N. Michigan Ave
Suite 3106
Chicago, Illinois 60611

Re: K170372
Trade/Device Name: SpiralTech Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 29, 2017
Received: June 5, 2017

Dear Daniel Rosenthal:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Andrew I. Steen -S

for Lori A. Wiggins, MPT, CLT
Acting 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)*
K170372

Device Name
SpiralTech Dental Implant System

Indications for Use *(Describe)*
The Spiraltech Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth , in order to restore patients esthetics and chewing function. Spiraltech implants are intended for single or multiple unit restorations on splinted or non-splinted applications. The implants ESi Dynamic and Ultimate are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants [along with Premium and One Piece] can also be used for loading after a conventional healing period.

Solo One Piece 3.0 and 3.3 implants, Ultimate (conical) 3.0 implants, and ESi (conical) 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.0 and/or 3.3 implants adjacent to one another.

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 June 17, 2017

SpiralTech Dental Implants

Company: SpiralTech Superior Dental Implants

Address: 875 N. Michigan Ave Suite 3106 Chicago, IL 60611

Phone: 312-440-7777

Contact Person: Daniel Rosenthal

Contact email: info@spiraltech.com

Trade Name: SpiralTech Dental Implant System

Common Name: dental implant and abutment system

Classification Name: endosseous dental implant

Regulation Number: 21 CFR 872.3640

Product Code: DZE

Secondary Product Code: NHA

Predicate Device: Nobel Biocare K071370

Reference Devices: Implants – Nobel Biocare K133731 K020646 K102436 Biohorizons K121787 Zimmer K082639 MIS K080162 K103089 Abutments - Biohorizons K071638 Alpha Bio Tec K063364 MSI K112162

Indications for Use

The Spiraltech Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patients esthetics and chewing function. Spiraltech implants are intended for single or multiple unit restorations on splinted or non-splinted applications. The implants ESi Dynamic and Ultimate are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants [along with Premium and One Piece] can also be used for loading after a conventional healing period.

Solo One Piece 3.0 and 3.3 implants, Ultimate (conical) 3.0 implants, and ESi (conical) 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.0 and/or 3.3 implants adjacent to one another.

Device Description

The SpiralTech implant system is a comprehensive product line that includes implants, corresponding abutments, and closure screws. SpiralTech dental implants are grade 5 titanium (Ti 6Al-4V ELI, conforms to ASTM F136) implants that come in 2 different surface treatments - SLA, and RBM.

SpiralTech dental implants come in five product lines with four based on their thread designs. The ESi has sharp, square, and rounded threads. The Ultimate and Dynamic lines also have sharp threads with the Dynamic having a reverse buttress thread design. The Premium line features square and sharper threads in a more conventional design. The implants have diameters ranging from 3.0 mm to 6.0 mm, and the lengths from 8mm to 15 mm. ESi, Ultimate, and Dynamic are intended to be used for immediate loading. The fifth implant type is the One Piece which comes with an abutment which cannot be used with low mechanical stability cases.

Abutments are available in various types including straight, shoulder, angulated, ball attachments, multi-unit, temporary and healing. All abutments come in both hex and conical connections. Temporary abutments come in PEEK and zirconia. Healing abutments come in titanium alloy and zirconia. Abutments come in titanium alloy and as a titanium base with zirconia abutment. Ball attachments and multi-units are titanium alloy. No SpiralTech abutments are intended to be modified.

Sizes

The Hex versions of the designs are available in 3.3, 3.5, 4.3, 5.0, and 6.0 with lengths 8, 10, 11, 13, and 15. The conical versions start at a diameter of 3.5 but are otherwise available in the same sizes and lengths with one exception, the Ultimate and ESi designs also come in 3.0 diameter with lengths of 10, 11, 13, and 15.

Hex version implant sizes:

Diameter (mm)	Implant Lengths (mm)
3.3mm	8, 10, 11.5, 13, 15mm
3.5mm	8, 10, 11.5, 13, 15mm
4.3mm	8, 10, 11.5, 13, 15mm
5.0mm	8, 10, 11.5, 13, 15mm
6.0mm	8, 10, 11.5, 13, 15mm

Conical version implant sizes:

Diameter (mm)	Implant Lengths (mm)
3.0mm	10, 11.5, 13, 15mm – *only for Ultimate and ESi implants*
3.5mm	8, 10, 11.5, 13, 15mm
4.3mm	8, 10, 11.5, 13, 15mm
5.0mm	8, 10, 11.5, 13, 15mm
6.0mm	8, 10, 11.5, 13, 15mm

The Solo one piece implant comes in diameters 3.0, 3.3, 3.75, and 4.2. It has lengths of 10, 11, 13 and 15.

The smallest diameter conical versions for the ESi, Ultimate, Dynamic and Premium implants are only compatible with the 0° and 15° titanium conical abutment models.

The smallest diameter hex versions for the ESi, Ultimate, Dynamic and Premium implants are only compatible with the 0°, 15° and 25° titanium hex abutment models.

Non-Clinical Testing

Sterilization validation was conducted for the implants and abutments according to the respective standards, ISO 11737-1, ISO 11737-2, ISO 11137-1, ISO 11137-2, and ISO 11137-3 (for gamma radiation validation) and ISO 17665-1 and ISO 17665-2 (for moist heat validation). This testing included USP 85, USP 161 and LAL method testing on the implants. The shelf life for the implants supplied sterile is 5 years based on accelerated testing (ASTM F1980) with one year of real time data (ASTM F1929-12, ASTM F88/F88M).

Several designs of SpiralTech Dental Implants were fatigue tested according to ISO 14801. Justification was provided to show the design tested was the worst case for that connection type. The implants with SLA and RBM surface treatments were evaluated by SEM and EDS for surface analysis.

The temporary abutments are made of PEEK. The implants are Ti6Al4V with either SLA or RBM surface treatment. Abutments are either Ti6AL4V or $ZrO_{2.}$ Chemical characterization of the ZrO_2 was provided. Cytotoxicity (MEM elution) has been provided to demonstrate biocompatibility for all subject devices composed of these identified materials.

Substantial Equivalence

The widths and lengths of the implants are in the same range as the predicate and reference devices. The materials used for all the devices are commonly used in dentistry and are used in the predicate and reference devices. As can be seen in the table, the thread designs incorporate types of threads used in the predicate and reference devices. The implant connections types are ones used in several predicate devices as can be seen in the table. The indications for use are the same as the predicate device, except for adding more restrictive placement for the Solo One Piece 3.0 and 3.3 implants, Ultimate (conical) 3.0 implants, and ESi (conical) 3.0 implants. The surface treatments available are the same types as those used on predicate devices.

The testing done for sterilization validation is the same type of testing done on the predicate and reference devices. Also the predicate and reference devices underwent the same ISO 14801 testing.

See the Substantial Equivalence Tables.

Conclusion

The SpiralTech Dental Implants are substantially equivalent to the predicate device based on design including implant connection, materials, surface treatments, dimensions, and testing completed.

Substantial Equivalence Table

Implant Table

	SpiralTech	NobelActive K071370 and K133731	NobelReplace K020646	NobelActive 3.0 K102436	Internal Tapered Plus from Biohorizons K121787	Tapered SwissPlus from Zimmer K082639	MIS Uno K080162	MIS Short implants K103089
Material	Ti6Al4V	CP Titanium	Ti6Al4V	CP Titanium	Ti6Al4V	Ti6Al4V	Ti6Al4V	Ti6Al4V
Diameters	3.0 – 6.0 with the exact sizes varying among the designs.	3.5, 4.3, 5.0, 5.5	3.5, 4.3, 5.0, 6.0	3.0	3.8, 4.6, 5.8	3.7, 4.8	3.0 and 3.5	4.2, 5.0, 6.0
Lengths	8, 10, 11, 13, 15 with not all lengths available for all sizes and designs	8.5, 10, 11.5	10, 13, 16	10, 11.5, 13, 15	7.5, 9, 10.5, 12, 15	8, 10, 12, 14	10, 13, 16	6.0
Indications for Use	The Spiraltech Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to	Nobel Biocare's NobelActive implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw						

	provide support for prosthetic devices, such as an artificial tooth , in order to restore patients esthetics and chewing function. Spiraltech implants are intended for single or multiple unit restorations on splinted or non-splinted applications. The implants ESi Dynamic and Ultimate are intended for immediate loading when good primary stability is achieved,	arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's Nobelactive implants are indicated for single or multiple unit restorations in splinted and non-splinted applications. Nobel Biocare's NobelActive implants are intended for immediate loading when good primary						

	and with appropriate occlusive loading. These implants [along with Premium and One Piece] can also be used for loading after a conventional healing period. Solo One Piece 3.0 and 3.3 implants, Ultimate (conical) 3.0 implants, and ESi (conical) 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral	stability is achieved and with appropriate occlusal loading.						

	incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.0 and/or 3.3 implants adjacent to one another.							
ESI thread design reference device						X		
Dynamic thread design reference device					X			
Premium thread design reference device			X					
Ultimate thread design reference and predicate		X						

device								
One Piece thread design reference and predicate device							X	
Radiation Sterilization of the Implants	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Validated Steam Sterilization Instructions supplied for abutments	Yes	Yes	Yes	Yes	Yes	Yes	No abutments	Yes
Subject of Fatigue testing meeting ISO 14801	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Connection interface	hex, conical	hex	conical	hex	hex	octagon	N/A	hex
Surface Treatments Available	SLA, RBM	Acid etched	HA, acid etched	TiUnite	RBM	HA, RBM	SLA	SLA

Abutment Table

Abutments		Hex	Conical NP	Conical RP	Slim Conical
Flat Titanium Straight	3.8 (Narrow)	Facial Heights – 5,7,9,11	Facial Heights – 5,7,9,11	Facial Heights – 5,7,9,11	
Flat Titanium Straight	4.5 (Standard)	Facial Heights – 5,7,9,11	Facial Heights – 5,7,9,11	Facial Heights – 5,7,9,11	
Flat Titanium Straight	5.5 (Wide)	Facial Heights – 5,7,9,11		Facial Heights – 5,7,9,11	
Flat Titanium Shoulder	3.8	Facial Heights – 1,2,3	Facial Heights – 1,2,3,4	Facial Heights – 1,2,3	
Flat Titanium Shoulder	4.5	Facial Heights – 1,2,3	Facial Heights – 1,2,3,4	Facial Heights – 1,2,3	
Flat Titanium Shoulder	5.5	Facial Heights – 1,2,3	Facial Heights – 1,2,3,4	Facial Heights – 1,2,3	
Anatomic Titanium	4.5	Facial Heights – 1,2,3,4	Facial Heights – 1,2,3,4	Facial Heights – 1,2,3,4	
Anatomic Titanium	5.5	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	
15 Degree Angulated –	4.7	Facial Heights –	Facial Heights –	Facial Heights –	

Titanium		1,2,3	1,2,3	1,2,3	
25 Degree Angulated – Titanium	5.2	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	
30 Degree Angulated – Titanium	5.3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	
Flat Titanium Slim	3.7				Facial Heights – 1,2,3
15 degree Angulated Titanium slim	3.7				Facial Heights – 1,2,3
Titanium Multiunit Abutments - Straight	-	Facial Heights – 1,2,3,4	Facial Heights – 1,2,3,4	Facial Heights – 1,2,3,4	
Titanium Multiunit Abutments – 17 Degree angulated	-	Facial Heights – 1,2,3,4	Facial Heights – 1,2,3,4	Facial Heights – 1,2,3,4	
Titanium Multiunit Abutments – 30 degree angulated	-	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	
Titanium Healing Abutment	3.8	Facial Heights – 2,3,4,5,6	Facial Heights – 2,3,4,5,6	Facial Heights – 2,3,4,5,6	
Titanium Healing	4.5	Facial Heights –	Facial Heights –	Facial Heights –	

Abutment		2,3,4,5,6	2,3,4,5,6	2,3,4,5,6	
Titanium Healing Abutment	5.5	Facial Heights – 2,3,4,5,6	Facial Heights – 2,3,4,5,6	Facial Heights – 2,3,4,5,6	
Zirconia Anatomic Abutments	4.5	Facial Heights – 1,2,3	Facial Heights – 1,2,3		
Zirconia Healing Abutment	3.8	Facial Heights – 2,3,4,5,6	Facial Heights – 2,3,4,5,6	Facial Heights – 2,3,4,5,6	
Zirconia Healing Abutment	5.5	Facial Heights – 3,4		Facial Heights – 3,4	
PEEK Temporary Flat Abutments	Length - 10	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	
PEEK Temporary Flat Abutments	Length - 11	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	
PEEK Temporary Flat Abutments	Length - 12	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	
PEEK Temporary anatomic Abutments	Length - 10	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	
PEEK Temporary Anatomic Abutments	Length - 11	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	
PEEK Temporary Anatomic	Length - 12	Facial Heights – 1,2,3	Facial Heights – 1,2,3	Facial Heights – 1,2,3	

Abutments					
Implant Prosthetic Indicator	-	Facial Heights – 1,2,3,4,5,6	Facial Heights – 1,2,3,4,5,6	Facial Heights – 1,2,3,4,5,6	
Ball Attachments	-	Facial Heights – 1,2,3,4,5,6	Facial Heights – 1,2,3,4,5,6	Facial Heights – 1,2,3,4,5,6	

Predicate Device Comparison for SpiralTech Abutments				
	SpiralTech (Internal Hex and Conical Connection)	**Biohorizon** (Conical Internal Hex) K071638	**Alpha Biotec** (Internal Hex Connection) K063364	**MIS** (Internal Hex) K112162
Straight Titanium Abutments	Diameters – 3.8,4.5,5.5 Facial Heights – 5,7,9,11	Laserlok Simple abutments Diameters – 3.8,4.5,5.5 Facial Heights – 5,7,9,11	Titanium Abutments Diameters –3.85,4.5,5.3 Facial Heights – 6,7,8,9	Straight Titanium Abutments Diameters – 3.8,4.5,5.5 Facial Heights – 5,7,9,11
Anatomic Titanium abutments	Diameter – 4.5 Facial Heights – 1,2,3,4 Diameter – 5.5 Facial Heights – 1,2,3	Straight Esthetic connections Diameters – 3.0,3.5,4.5,5.7 Facial Heights – 1,2,3	Anatomic Abutments with Emergence Profile Diameter – 4.3 Facial Heights – 1.5,2 Diameter – 5.5 Facial Heights – 2,3	
Shoulder Titanium abutments	Diameter – 3.8 Facial Heights – 1,2,3 Diameter – 4.5 Facial Heights – 1,2,3,4 Diameter – 5.5 Facial Heights – 1,2,3		Straight abutments with various cuff heights Diameter – 3.85 Facial Heights – 0.5,1.5,2.5 Diameter – 4.8 Facial Heights – 1,2,3,4 Diameter – 5.6 Facial Heights – 2,4	
Angulated titanium abutments	15 Degree – Diameter – 4.7 - Heights – 1,2,3 25 Degree – Diameter – 5.2 - Heights – 1,2,3 30 Degree – Diameter – 5.3 - Heights – 2,3,4,5	15 Degree – Diameter – 4.5,5.7 - Heights – 2,3 25 Degree – Diameter – 5.2 - Heights – 1,2,3 30 Degree – Diameter – 5.3 - Heights – 2,3,4,5	Angled Abutments 15 Degree – Diameter – 4.5,4.8,5.1 - Heights – 1,2,3 25 Degree – Diameter – 4.7, 5.3 - Heights – 1,2,3	

			35 Degree – Diameter – 4.65, 5.3 - Heights – 1,2,3	
Titanium Healing abutments	Diameter – 3.8 Facial Heights – 2,3,4,5,6 Diameter – 4.5 Facial Heights – 2,3,4,5,6 Diameter – 5.5 Facial Heights – 2,3,4,5,6	Titanium Healing abutments Diameter – 3.8 Facial Heights – 1,3,5 Diameter – 4.7 Facial Heights – 1,3,5 Diameter – 5.7 Facial Heights – 1,3,5	Titanium Healing abutments Diameter – 3.8 Facial Heights – 3,4,5 Diameter – 4.5 Facial Heights – 2,3,4,5,6,7 Diameter – 5, 5.5,6,7,7.8 Facial Heights – 3,5	Titanium Healing abutments Diameter – 3.8 Facial Heights – 2,3,4,5,6,7 Diameter – 5.5 Facial Heights – 3,4,5,6
Zirconia Abutments - Anatomic	Diameter – 4.5 Facial Heights – 1,2,3			Straight Anatomic Zirconia Diameter – 4.5 Facial Heights – 1,2,3,4
Zirconia Healing abutments				
Multi unit abutments	Straight Diameter – 4.7 Facial Heights – 1,2,3,4 17 Degree Diameter – 5.3 Facial Heights –1,2,3 30 Degree Diameter – 5.4 Facial Heights – 1,2,3	Multi unit abutments Straight Diameter – 4.5 Facial Heights – 1,2,3,4,5 17 Degree Diameter – 4.5 Facial Heights –2.25,3,4 30 Degree Diameter – 3.5,4.5	Straight Diameter – 4.7 Facial Heights – 1.5,2.5,3,4,5 17 Degree Diameter – 5.3 Facial Heights –2,3 30 Degree Diameter – 5.4 Facial Heights – 2,3	Straight Diameter – 4.7 Facial Heights – 1,2,3,4,5,6 17 Degree Diameter – 5.3 Facial Heights –2,3 30 Degree Diameter – 5.4 Facial Heights – 2,3

		Facial Heights – 3,4,5		
PEEK temporary abutments Straight	Diameter – 4.5 Facial Heights – 1,2,3	Temporary PEEK abutments Diameter – 3.0,3.5,4.5,5.7 Facial Heights – 3		
PEEK temporary abutments Anatomic	Diameter – 4.5 Facial Heights – 1,2,3		Temporary PEEK abutments Diameter – 5.4 Facial Heights – 1,2,3	
Ball attachments	Heights – 1,2,3,4,5,6	Ball attachments Diameter – 4.5 Facial Heights – 1,3,5	Titanium Ball attachments Heights – 0.5,2,3,4,5,6	Titanium Ball attachments Heights – 1,2,3,4,5,6