November 16, 2020

Nobel Biocare AB
Bernice Jim
Regulatory Affairs Manager
Box 5190, SE-402 26
Vastra Hamngatan 1, Gotlands Län [SE-09] 411 17
SWEDEN

Re: K202344
Trade/Device Name: TiUltra Implants and Xeal Abutments
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA, PNP
Dated: August 17, 2020
Received: August 18, 2020

Dear Bernice Jim:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202344

Device Name
TiUltra Implants and Xeal Abutments

Indications for Use *(Describe)*

NobelActive TiUltra

NobelActive TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

NobelActive TiUltra implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

NobelActive TiUltra 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

NobelActive TiUltra 3.0 implants are indicated for single-unit restorations only.

NobelReplace CC TiUltra

NobelReplace CC TiUltra implants are endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function.

The NobelReplace CC TiUltra implants are indicated for single or multiple unit restorations. The NobelReplace CC TiUltra implants can be used in splinted or non-splinted applications. The NobelReplace CC TiUltra implant may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

NobelParallel CC TiUltra

NobelParallel CC TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function.

NobelParallel CC TiUltra implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

Implants with <7 mm length are for delayed loading only when appropriate stability has been achieved.

Remaining indications are continued on a separate page.

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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INDICATIONS FOR USE FORM 3881 ATTACHMENT: INDICATIONS FOR USE (CONT.)

MUA Xeal

The MUA Xeal is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

On1 Base Xeal

The On1 Base Xeal device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. The On1 Universal Abutments consist of three major parts. Specifically, the On1 Base Xeal, the On1 Universal Abutment, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

510(k) Notification K202344

Submitter

Nobel Biocare AB
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Sweden

Submitted by:
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Date Prepared: 16 November 2020

Device

Trade Name: TiUltra Implants and Xeal Abutments
Generic/Common Name: Endosseous Dental Implants and Abutments
Regulation Name: Endosseous Dental Implant
Regulation Number: 21 CFR 872.3640
Regulatory Class: II
Product Code: DZE
Secondary Product Code: NHA, PNP

Predicate Devices

Table 1: Predicate Devices for the TiUltra implants and Xeal abutments

	Device	510(k)	Manufacturer
Primary Predicate	NobelActive	K142260	Nobel Biocare AB
Predicate #2	NobelReplace Hexagonal Implant	K073142	Nobel Biocare AB
Predicate #3 and Reference #2	NobelParallel Conical Connection	K173418	Nobel Biocare AB
Predicate #4	Multi-unit Abutment Plus	K161416	Nobel Biocare AB
Predicate #5	On1 Universal Abutment	K181869	Nobel Biocare AB
Reference #1	BTI Dental Implant System UnicCa®	K151391	B.T.I. Biotechnology Institute
Reference #3	ST Internal Implant System	K192347	MegaGen Implant Co., Ltd.

Device Description

The TiUltra implants and Xeal abutments are endosseous dental implants and abutments with an internal conical connection (CC) with hex interface. The TiUltra implants are comprised of three implant lines with various body shapes, range of diameters (3.0 – 5.5mm), and lengths (6.5 – 18mm). The Xeal abutments are comprised of specific abutment types (i.e., straight, angled, and base). Both the TiUltra implants and Xeal abutments are made of titanium and feature a surface treatment that preserves the hydrophilicity of the device.

In compliance with the FDA Guidance Document entitled, "*Bundling Multiple Devices or Multiple Indications in a Single Submission*," issued June 22, 2007, Nobel Biocare is pursuing a single submission for both the TiUltra implants and Xeal abutments because this submission represents the enactment of a similar change across multiple device lines as listed in Table 2 below.

Table 2: Devices Included in this 510(k) Submission

Subject Device	Device Lines	Description
TiUltra implants	NobelActive® TiUltra™	Endosseous dental implant
	NobelReplace® Conical Connection (CC) TiUltra™	Endosseous dental implant
	NobelParallel™ Conical Connection (CC) TiUltra™	Endosseous dental implant
Xeal abutments	Multi-unit Abutment Xeal™	Endosseous dental abutment
	On1 Base Xeal™	Endosseous dental abutment

An overview of TiUltra implants and Xeal abutments: platforms, diameters, lengths, collar heights, and abutment angles are provided below in Table 3 and Table 4, respectively.

Table 3: TiUltra implant Product Range

Subject Device	Implant Lines	Platform	Diameter (mm)	Length (mm)
TiUltra implants	NobelActive TiUltra	3.0	3.0	10.0, 11.5, 13.0, 15.0
		NP	3.5	8.5, 10.0, 11.5, 13.0, 15.0, 18.0
		RP	4.3	8.5, 10.0, 11.5, 13.0, 15.0, 18.0
			5.0	8.5, 10.0, 11.5, 13.0, 15.0, 18.0
		WP	5.5	7.0, 8.5, 10.0, 11.5, 13.0, 15.0
	NobelReplace CC TiUltra	NP	3.5	8.0, 10.0, 11.5, 13.0, 16.0
		RP	4.3	8.0, 10.0, 11.5, 13.0, 16.0
			5.0	8.0, 10.0, 11.5, 13.0, 16.0
	NobelParallel CC TiUltra	NP	3.75	6.5, 8.0, 9.5, 11.0, 12.5, 14.5, 17.5
		RP	4.3	6.5, 8.0, 9.5, 11.0, 12.5, 14.5, 17.5
			5.0	6.5, 8.0, 9.5, 11.0, 12.5, 14.5, 17.5
		WP	5.5	6.5, 8.0, 9.5, 11.0, 12.5, 14.5

Table 4: Xeal abutment Platform Variations

Subject Device	Abutment Line	Abutment Angle	Platform	Collar Height (mm)
Xeal abutments	Multi-unit Abutment Xeal (MUA)	0° (straight)	NP	1.5, 2.5, 3.5
			RP	1.5, 2.5, 3.5, 4.5
			WP	1.5, 2.5, 3.5
		17°	NP	2.5, 3.5
			RP	2.5, 3.5
			WP	2.5, 3.5
		30°	NP	3.5, 4.5
			RP	3.5, 4.5
	On1 Base Xeal	Base	NP	1.75, 2.5
		Base	RP	1.75, 2.5
		Base	WP	1.75, 2.5

The proposed On1 Base Xeal abutments is utilized with the On1 Universal Abutments. The On1 Universal Abutments are always to be used as multi-piece abutments, incorporating use of a

coronal ceramic mesostructure or hybrid abutment/crown and dental cement for bonding the components.

The On1 Universal Abutment is a dental implant abutment which attaches to the On1 Base of the On1 Concept (K161655) and is intended to be used with the current Nobel Biocare dental implants that have the existing internal conical connection.

The On1 Universal Abutment features a fixed upper shape with indexing feature that is intended to serve as the platform for either an in-laboratory CAD/CAM system made mesostructure or abutment crown. The fixed upper shape and indexing feature facilitates the use of CAD/CAM systems by providing a known shape that can be imported into the design software, thereby, simplifying the CAD/CAM design process.

The digital workflow requires the use of the following equipment:

- Scanner: 3Shape intra oral scanner Trios (3Shape A/S)
- Design Software: 3Shape Abutment Designer Software (3Shape A/S) - K151455 where the Implant Libraries are obtained via the 3Shape server in the software
- Restorative Material: Enamic (Vita Zahnfabrik H. Rauter GmbH Co) - K153645
- Milling Unit: CORiTEC, imes-icore milling unit

The following restorative design specifications is required:

Restorative design specifications for Universal Base	
Parameter	Specification
Angle from axis of the implant	20° Max
Wall Thickness Circular	0.8mm min.
Wall Thickness Margin	0.275mm min.
Post Height	5.2mm min.
Maximum Length, width and Height	EM-14 blank 12x14x18mm EM-10 blank 8x10x15mm

Indications for Use

NobelActive TiUltra

NobelActive TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.

NobelActive TiUltra implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

NobelActive TiUltra 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible.

NobelActive TiUltra 3.0 implants are indicated for single-unit restorations only.

NobelReplace CC TiUltra

NobelReplace CC TiUltra implants are endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function.

The NobelReplace CC TiUltra implants are indicated for single or multiple unit restorations. The NobelReplace CC TiUltra implants can be used in splinted or non-splinted applications. The NobelReplace CC TiUltra implant may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

NobelParallel CC TiUltra

NobelParallel CC TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function.

NobelParallel CC TiUltra implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.

Implants with <7mm length are for delayed loading only when appropriate stability has been achieved.

MUA Xeal

The MUA Xeal is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

On1 Base Xeal

The On1 Base Xeal device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. The On1 Universal Abutments consist of three major parts. Specifically, the On1 Base Xeal, the On1 Universal Abutment, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral

Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Comparison of Technological Characteristics

TiUltra Implants

The intended use and Indications for Use for each TiUltra implant subject device is the same as each respective predicate. The subject and respective predicate devices are endosseous dental implants to support prosthetic devices in order to restore patient esthetics and chewing function. Therefore, the devices are substantially equivalent in consideration of the intended use and Indications for Use.

Further, the devices are highly consistent with respect to technological characteristics. The sets of devices have the same material, device implant length and width, platforms, connection shape and macro design. There are a few technological differences between the subject devices and their respective predicate devices, which do not raise different questions of substantial equivalence, summarized as follows: surface topography (roughness and thickness), surface preservation, implant/abutment connection, and packaging. The TiUltra implants' surface roughness and corresponding oxide layer thicknesses are within the range of the TiUnite – Gradient surface featured on NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2). The surface roughness, oxide layer thicknesses of the multi-level anodization and salt surface preservation differences did not raise different questions of safety and effectiveness as demonstrated by fatigue testing, surface characterization, and performance testing via an animal study. Therefore, the summarized differences between the TiUltra implant subject device and predicate devices do not raise different questions of substantial equivalence as confirmed by respective verification and validation testing. Therefore, the subject and predicate devices are substantially equivalent.

Xeal Abutments

The intended use and Indications for Use for each Xeal abutment subject device is the same as each respective predicate. The subject and respective predicate devices are intended to be used with endosseous dental implants and be used as an aid in prosthetic rehabilitation. Therefore, the devices are substantially equivalent in consideration of the intended use and Indications for Use.

Further, the subject and predicate devices are highly consistent with respect to technological characteristics. The sets of devices have the same compatible implant platforms, material, abutment height and width, abutment angulation, surface topography, and packaging. There are two technological differences between the subject devices and their respective predicate devices, which do not raise different questions of substantial equivalence, summarized as follows: surface treatment and surface preservation. The summarized differences between the Xeal abutment subject device and predicate devices do not raise different questions of substantial equivalence as confirmed by respective verification and validation testing. Therefore, the subject and predicate devices are substantially equivalent.

Table 5: Comparison of the TiUltra implants with Predicate Implants

Technological Characteristics	Subject Device TiUltra Implants	Predicate Device NobelActive (K142260 – Primary Predicate)	Predicate Device NobelReplace Hexagonal Implant (K073142 – Predicate #2)	Predicate Device NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2)[1]	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
Pictorial Representation	**NobelActive TiUltra**  **NobelReplace CC TiUltra**  **NobelParallel CC TiUltra** 				N/A	--
Regulatory Classification	21 CFR 872.3640 Endosseous dental implant	21 CFR 872.3640 Endosseous dental implant	21 CFR 872.3640 Endosseous dental implant	21 CFR 872.3640 Endosseous dental implant	21 CFR 872.3640 Endosseous dental implant	All devices have the regulatory classification, 21

[1] NobelParallel Conical Connection K173418 is Predicate #3 for NobelParallel CC TiUltra (subject device) and Reference #2 for NobelActive and NobelReplace CC TiUltra (subject devices)

Table 5: Comparison of the TiUltra implants with Predicate Implants (Cont.)

Technological Characteristics	Subject Device TiUltra Implants	Predicate Device NobelActive (K142260 – Primary Predicate)	Predicate Device NobelReplace Hexagonal Implant (K073142 – Predicate #2)	Predicate Device NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2)[1]	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
						CFR 872.3640, Endosseous dental implant.
Product Code	DZE	DZE, NHA	DZE	DZE	DZE	All devices have the product code, DZE.
Indications for Use	**NobelActive TiUltra** NobelActive TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive TiUltra implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive TiUltra 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive TiUltra 3.0 implants are indicated for single-unit restorations only. **NobelReplace CC TiUltra** NobelReplace CC TiUltra implants are endosseous	NobelActive implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive 3.0 implants are indicated for single-unit restorations only.	Nobel Biocare's NobelReplace Hexagonal Implants are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The NobelReplace Hexagonal Implants are indicated for single or multiple unit restorations. The NobelReplace Hexagonal Implants can be used in splinted or non-splinted applications. The NobelReplace Hexagonal Implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.	NobelParallel Conical Connection implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function. NobelParallel Conical Connection implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants with <7mm length are for delayed loading only when appropriate stability has been achieved.	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function. In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations. In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.	NobelActive TiUltra has the same Indications for Use as NobelActive (K142260 – Primary Predicate). NobelReplace CC TiUltra has the same Indications for Use as NobelReplace Hexagonal Implant (K073142 – Predicate #2). NobelParallel CC TiUltra has the same Indications for Use as NobelParallel Conical Connection (K173418 – Predicate #3).

Table 5: Comparison of the TiUltra implants with Predicate Implants (Cont.)

Technological Characteristics	Subject Device TiUltra Implants	Predicate Device NobelActive (K142260 – Primary Predicate)	Predicate Device NobelReplace Hexagonal Implant (K073142 – Predicate #2)	Predicate Device NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2)[1]	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
	dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The NobelReplace CC TiUltra implants are indicated for single or multiple unit restorations. The NobelReplace CC TiUltra implants can be used in splinted or non-splinted applications. The NobelReplace CC TiUltra implant may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied. **NobelParallel CC TiUltra** NobelParallel CC TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function. NobelParallel CC TiUltra implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or					

Table 5: Comparison of the TiUltra implants with Predicate Implants (Cont.)

Technological Characteristics		Subject Device TiUltra Implants	Predicate Device NobelActive (K142260 – Primary Predicate)	Predicate Device NobelReplace Hexagonal Implant (K073142 – Predicate #2)	Predicate Device NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2)[1]	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
		delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants with <7mm length are for delayed loading only when appropriate stability has been achieved.					
Design Features	**Implant Length**	**NobelActive TiUltra** 7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm **NobelReplace CC TiUltra** 8.0, 10.0, 11.5, 13.0, 16.0mm **NobelParallel CC TiUltra** 6.5, 8.0, 9.5, 11.0, 12.5, 14.5, 17.5mm	7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm	8.0, 10.0, 13.0, 16.0mm	6.5, 8.0, 9.5, 11.0, 12.5, 14.5, 17.5mm	Interna : 5.5, 6.5, 7.5, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm Externa : 7.5, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm	NobelActive TiUltra has the same implant lengths as NobelActive (K142260 – Primary Predicate). NobelReplace CC TiUltra has the same implant lengths as NobelReplace Hexagonal Implant (K073142 – Predicate #2). NobelParallel CC TiUltra has the same implant lengths as NobelParallel Conical Connection (K173418 – Predicate #3).
	Implant Diameter	**NobelActive TiUltra** 3.0, 3.5, 4.3, 5.0, 5.5mm **NobelReplace CC TiUltra** 3.5, 4.3, 5.0mm **NobelParallel CC TiUltra** 3.75, 4.3, 5.0, 5.5mm	3.0, 3.5, 4.3, 5.0, 5.5mm	3.5, 4.3, 5.0mm	3.75, 4.3, 5.0, 5.5mm	Interna : 3.3, 3.5, 3.75, 4.0, 4.25, 4.5, 5.0, 5.5, 6.0mm Externa :3.0, 3.3, 3.5, 3.75, 4.0, 4.5, 5.0, 5.5mm	NobelActive TiUltra has the same implant diameter as NobelActive (K142260 – Primary Predicate). NobelReplace CC TiUltra has the same implant diameter as NobelReplace Hexagonal Implant (K073142 – Predicate #2). NobelParallel CC TiUltra has the same implant diameter as NobelParallel Conical Connection (K173418 – Predicate #3).

Table 5: Comparison of the TiUltra implants with Predicate Implants (Cont.)

Technological Characteristics		Subject Device TiUltra Implants	Predicate Device NobelActive (K142260 – Primary Predicate)	Predicate Device NobelReplace Hexagonal Implant (K073142 – Predicate #2)	Predicate Device NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2)[1]	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
	Platform Compatibility	**NobelActive TiUltra** • 3.0 Platform • Narrow Platform (NP) • Regular Platform (RP) • Wide Platform (WP) **NobelReplace CC TiUltra** • Narrow Platform (NP) • Regular Platform (RP) **NobelParallel CC TiUltra** • Narrow Platform (NP) • Regular Platform (RP) • Wide Platform (WP)	• 3.0 Platform • Narrow Platform (NP) • Regular Platform (RP) • Wide Platform (WP)	• Narrow Platform (NP) • Regular Platform (RP)	• Narrow Platform (NP) • Regular Platform (RP) • Wide Platform (WP)	N/A	NobelActive TiUltra has the same platform compatibility as NobelActive (K142260 – Primary Predicate). NobelReplace CC TiUltra has the same platform compatibility as NobelReplace Hexagonal Implant (K073142 – Predicate #2). NobelParallel CC TiUltra has the same platform compatibility as NobelParallel Conical Connection (K173418 – Predicate #3).
	Connection Type	Internal conical connection with hex interface	Internal conical connection with hex interface	Internal conical connection with hex interface	Internal conical connection with hex interface	Internal (Interna) and External (Externa)	The subject and predicate devices have the connection type, Internal conical connection with hex interface.
	Macro Design	**NobelActive TiUltra** Tapered implant with back-tapered coronal design, reverse-cutting flutes and double lead threads **NobelReplace CC TiUltra** Tapered implant with single lead threads **NobelParallel CC TiUltra** Double lead thread with groove; Tapered apex	Tapered implant with back-tapered coronal design, reverse-cutting flutes and double lead threads	Tapered implant with single lead threads	Double lead thread with groove; Tapered apex with bone cutting flutes, slightly tapered body	Threaded, root form	NobelActive TiUltra has the same macro design as NobelActive (K142260 – Primary Predicate). NobelReplace CC TiUltra has the same macro design as NobelReplace Hexagonal Implant (K073142 – Predicate #2). NobelParallel CC TiUltra has the same macro design as NobelParallel Conical

Table 5: Comparison of the TiUltra implants with Predicate Implants (Cont.)

Technological Characteristics		Subject Device TiUltra Implants	Predicate Device NobelActive (K142260 – Primary Predicate)	Predicate Device NobelReplace Hexagonal Implant (K073142 – Predicate #2)	Predicate Device NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2)[1]	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
		with bone cutting flutes, slightly tapered body					Connection (K173418 – Predicate #3).
	Material	Commercially pure titanium	Commercially pure titanium	Commercially pure titanium	Commercially pure titanium	Commercially pure titanium	The material used for all devices is commercially pure titanium.
	Surface Treatment	Anodic oxidation	Anodic oxidation	Anodic oxidation	Anodic oxidation	Grit blasted and acid etched, machined	The subject and predicate devices have the surface treatment, anodic oxidation.
	Implant/ Abutment connection	Anodic oxidation on collar and inside the connection	Machined on collar and inside the connection (NP and RP platforms) Anodic oxidation on collar and inside the connection (WP platform)	Anodic oxidation on collar and machined inside the connection	Anodic oxidation on collar and inside the connection	N/A	NobelActive TiUltra has the same implant/abutment connection as the wide platform NobelActive (K142260 – Primary Predicate) and NobelParallel Conical Connection (K173418 – Reference #2). The differences do not raise different questions of substantial equivalence as demonstrated by bench testing. NobelReplace CC TiUltra has a similar implant/abutment connection as NobelReplace Hexagonal Implant (K073142 – Predicate #2) and the same implant/abutment connection as NobelParallel Conical Connection (K173418 – Reference #2). The differences do not raise different questions of substantial equivalence as demonstrated by bench testing. NobelParallel CC TiUltra has the same implant/abutment connection as NobelParallel Conical Connection (K173418 – Predicate #3).

Table 5: Comparison of the TiUltra implants with Predicate Implants (Cont.)

Technological Characteristics		Subject Device TiUltra Implants	Predicate Device NobelActive (K142260 – Primary Predicate)	Predicate Device NobelReplace Hexagonal Implant (K073142 – Predicate #2)	Predicate Device NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2)[1]	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
	Surface Topography	TiUltra – Three level surface: • Level 0 (collar): o Sa (area roughness) = 0.5 ± 0.3µm o Thickness (Thk) = 0.166±0.008µm • Level 1 (transition): o Sa = 0.8 ± 0.3µm o Thk = 7.5±0.3µm • Level 2 (body): o Sa = 1.5 ± 0.4µm o Thk = 12.0±1.2µm	TiUnite – Single level surface: • Sa = 1.2 ± 0.5µm • Thk = 12.5±2.5µm	TiUnite – Single level surface: • Sa = 1.2 ± 0.5µm • Thk = 12.5±2.5µm	TiUnite – Gradient surface: • Level 0 (collar): machined, o Sa <1.6 µm o Thk = < 0.02µm • Level 1 (transition): o Sa = 0.8 ± 0.5µm o Thk ~10 ±2.5µm • Level 2 (body): o Sa = 1.2 ± 0.5µm o Thk ~12.5±2.5µm	Neck: Sq[2] 0.7 ± 0.1µm; Sdr[3] 50± 10% Thread: Sq≥ 1.2 µm; Sdr≥ 200% Valleys: Sq= 1.0 ± 0.2µm; Sdr= 85± 15%	The TiUltra implants' surface roughness, is within the range of NobelActive (K142260 – Primary Predicate) and NobelReplace Hexagonal Implant (K073142 – Predicate #2). The Device features multi-levels of anodization with a similar roughness and oxide layer thickness range as NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2). The differences do not raise different questions of substantial equivalence as demonstrated by bench and animal testing.
	Surface preservation	Hydrophilic surface Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt	N/A	N/A	N/A	UnicCa hydrophilic surface Soluble calcium chloride salt	The surface preservation is similar in composition and function as the soluble calcium chloride salt applied to BTI Dental Implant System UnicCa® (K151391 – Reference #1). The differences do not raise different questions of substantial equivalence as demonstrated by bench and animal testing.
Packaging		Polyethylene terephthalate (PET) vial with high density poly ethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister (2nd sterile barrier) inside	Polystyrene (PS) vial with protection elements. The vial is securely closed with HDPE cap forming a sterile barrier.	Polystyrene (PS) vial with protection elements. The vial is securely closed with HDPE cap forming a sterile barrier.	Polystyrene (PS) vial with protection elements. The vial is securely closed with HDPE cap forming a sterile barrier.	Unique container (vial with clamp)	Packaging differences do not raise different questions of substantial equivalence as demonstrated by bench testing.

[2] Sq: Root Square Mean Roughness.
[3] Sdr= Developed surface.

Table 5: Comparison of the TiUltra implants with Predicate Implants (Cont.)

Technological Characteristics	Subject Device TiUltra Implants	Predicate Device NobelActive (K142260 – Primary Predicate)	Predicate Device NobelReplace Hexagonal Implant (K073142 – Predicate #2)	Predicate Device NobelParallel Conical Connection (K173418 – Predicate #3 and Reference #2)[1]	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
	a cardboard box (protective packaging).					
Sterilization (SAL)	Gamma Radiation (SAL 10^{-6})	Gamma Radiation (SAL 10^{-6})	Gamma Radiation (SAL 10^{-6})	Gamma Radiation (SAL 10^{-6})	Gamma Radiation (SAL $1x10^{-6}$)	All devices are sterilized with Gamma Radiation (SAL $1x10^{-6}$).

Table 6: Comparison of the Xeal abutments with Predicate Devices

Technological Characteristics	Subject Device Xeal abutments	Predicate Device Multi-unit Abutment Plus (K161416 – Predicate #4)	Predicate Device On1 Universal Abutment (Base) (K181869 – Predicate #5)	Reference Device EZ Post Abutment for ST Internal Implant System (K192347 – Reference #3)	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
Pictorial Representation	**Multi-unit Abutment Xeal**  **On1 Base Xeal** 	 	On1 Universal Abutment  On1 Base 		N/A	
Regulatory Classification	21 CFR 872.3630 Endosseous dental implant abutment	21 CFR 872.3630 Endosseous dental implant abutment	21 CFR 872.3630 Endosseous dental implant abutment	21 CFR 872.3640 Endosseous dental implant	21 CFR 872.3640 Endosseous dental implant	The subject and predicate devices have the regulatory classification, 21 CFR 872.3630, Endosseous dental implant abutment.
Product Code	NHA	NHA	NHA, PNP	DZE, NHA	DZE	The subject and predicate devices have the product code, NHA.

Table 6: Comparison of the Xeal abutments with Predicate Devices (Cont.)

Technological Characteristics	Subject Device Xeal abutments	Predicate Device Multi-unit Abutment Plus (K161416 – Predicate #4)	Predicate Device On1 Universal Abutment (Base) (K181869 – Predicate #5)	Reference Device EZ Post Abutment for ST Internal Implant System (K192347 – Reference #3)	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
Indications for Use	**MUA Xeal** The MUA Xeal is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. **On1 Base Xeal** The On1 Base Xeal device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. The On1 Universal Abutments consist of three major parts. Specifically, the On1 Base Xeal, the On1 Universal Abutment, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	The On1™ device is a premanufactured prosthetic component directly connected to an endosseous implant and it is intended for use in prosthetic rehabilitation. The On1 Universal Abutments consist of three major parts. Specifically, the On1 Base, the On1 Universal Abutment, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function. In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations. In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.	MUA Xeal has the same Indications for Use as Multi-unit Abutment Plus (K161416 – Predicate #4). On1 Base Xeal has the same Indications for Use as On1 Universal Abutment (Base) (K181869 – Predicate #5).

Table 6: Comparison of the Xeal abutments with Predicate Devices (Cont.)

Technological Characteristics		Subject Device Xeal abutments	Predicate Device Multi-unit Abutment Plus (K161416 – Predicate #4)	Predicate Device On1 Universal Abutment (Base) (K181869 – Predicate #5)	Reference Device EZ Post Abutment for ST Internal Implant System (K192347 – Reference #3)	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
Design Features	**Compatible Implants Platforms**	Nobel Biocare Internal Conical Connection • Narrow Platform (NP) • Regular Platform (RP) • Wide Platform (WP)	Nobel Biocare Internal Conical Connection • Narrow Platform (NP) • Regular Platform (RP) • Wide Platform (WP)	Nobel Biocare Internal Conical Connection • Narrow Platform (NP) • Regular Platform (RP) • Wide Platform (WP)	Hex, Non-Hex	N/A	The subject and predicate devices are compatible with the NP, RP, and WP implant platforms.
	Abutment Height	**MUA Xeal** 1.5, 2.5, 3.5, 4.5mm **On1 Base Xeal** Combined base and post height • Temporary Abut – 8.3, 9.0mm • Esthetic Abut Ti – 8.2, 9.0mm • Esthetic Abut Zi – 8.2, 9.0mm	1.5, 2.5, 3.5, 4.5mm	Combined base and post height • Temporary Abut – 8.3, 9.0mm • Esthetic Abut Ti – 8.2, 9.0mm • Esthetic Abut Zi – 8.2, 9.0mm	Post Height: 4.0, 5.5, 7.0mm Gingival Height: 1.0, 2.0, 3.0, 4.0, 5.0mm	N/A	MUA Xeal has the same abutment height as Multi-unit Abutment Plus (K161416 – Predicate #4). On1 Base Xeal has the same abutment height as On1 Universal Abutment (Base) (K181869 – Predicate #5).
	Abutment Width	**MUA Xeal** 4.8mm **On1 Base Xeal** At base 4.8, 5.3, 6.5mm	4.8mm	At base 4.8, 5.3, 6.5mm	4.6, 5.0, 6.0, 7.0mm	N/A	MUA Xeal has the same abutment width as Multi-unit Abutment Plus (K161416 – Predicate #4). On1 Base Xeal has the same abutment width as On1 Universal Abutment (Base) (K181869 – Predicate #5).
	Abutment Angulation	**MUA Xeal** 0°, 17°, 30° **On1 Base Xeal** 0° angulation of the Base - 0-20° angulation of the ceramic mesostructure	0°, 17°, 30°	No abutment angulation	0°	N/A	MUA Xeal has the same abutment angulation as Multi-unit Abutment Plus (K161416 – Predicate #4). On1 Base Xeal has the same abutment angulation as On1 Universal Abutment (Base) (K181869 – Predicate #5).
	Material	Titanium vanadium alloy (ASTM F1472, ASTM F136)	Titanium vanadium alloy (ASTM F1472, ASTM F136)	Titanium vanadium alloy (ASTM F1472, ASTM F136)	Ti-6A1-4V ELI	Commercially Pure Titanium	The material used for the subject and predicate devices is Titanium vanadium alloy (ASTM F1472, ASTM F136).

Table 6: Comparison of the Xeal abutments with Predicate Devices (Cont.)

Technological Characteristics		Subject Device Xeal abutments	Predicate Device Multi-unit Abutment Plus (K161416 – Predicate #4)	Predicate Device On1 Universal Abutment (Base) (K181869 – Predicate #5)	Reference Device EZ Post Abutment for ST Internal Implant System (K192347 – Reference #3)	Reference Device BTI Dental Implant System UnicCa® (K151391 – Reference #1)	Comparison
	Abutment Surface Treatment	Anodization	No surface treatment	No surface treatment	Anodization	N/A	The subject devices and EZ Post Abutment for ST Internal Implant System (K192347 – Reference #3) have an anodization surface treatment. The differences do not raise different questions of substantial equivalence as demonstrated by bench testing.
	Abutment Surface Topography	Xeal – Single level surface • Sa <0.8µm	Machined – Single level surface • Sa <0.8µm	Machined – Single level surface • Sa <0.8µm	N/A	N/A	The subject and predicate devices have a surface roughness of Sa <0.8µm.
	Surface Preservation	Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate ($NaH_2PO_4 \cdot 2H_2O$) and magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$)	N/A	N/A	N/A	UnicCa hydrophilic surface Soluble calcium chloride salt	The surface preservation is similar in composition and function as the soluble calcium chloride salt applied to BTI Dental Implant System UnicCa® (K151391 – Reference #1). The differences do not raise different questions of substantial equivalence as demonstrated by bench and animal testing.
Abutment Packaging		Thermoformed polyethylene terephthalate glycol (PETG) tray with medical paper lid forming a sterile barrier.	Thermoformed PETG tray with medical paper lid forming a sterile barrier.	Thermoformed PETG tray with medical paper lid forming a sterile barrier.	N/A	N/A	The subject and predicate devices the packaging, thermoformed PETG tray with medical paper lid forming a sterile barrier.
Sterilization (SAL)		Gamma Radiation (SAL 10^{-6})	Gamma Radiation (SAL 10^{-6})	Gamma Radiation (SAL 10^{-6})	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Gamma Radiation (SAL $1x10^{-6}$)	The subject and predicate devices are sterilized with Gamma Radiation (SAL 10^{-6}).

Summary of Non-Clinical Testing

The following performance testing was submitted in this 510(k) to support substantial equivalence:

- **Sterilization Validation** in accordance with:
    - ISO 11137-1:2006, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
    - ISO 11137-2: 2013, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*
- **Endotoxin testing** was completed in accordance with:
    - USP 42-NF37:2019 <151>, *Medical Devices—Bacterial Endotoxin and Pyrogen Tests*
    - ANSI/AAMI ST72:2011/ (R)2016, *Bacterial endotoxins — Test methods, routine monitoring, and alternatives to batch testing*
- **Packaging performance testing** was conducted according to ISO 11607-1:2019, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- **Biocompatibility** was conducted according to ISO 10993-1:2018, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and includes:
    - Expert toxicity assessment;
    - Dissolution kinetics of the soluble salt (protective) layer;
    - Chemical characterization according to ISO 10993-18:2009, for the chemical characterization of leachables;
    - Cytotoxicity assessment according to ISO 10993-5:2009;
    - Sensitization testing according to ISO 10993-10:2010;
    - Irritation testing according to ISO 10993-10:2010;
    - Material – mediated pyrogenicity testing according to ISO 10993-11:2017; and
    - Acute systemic toxicity testing according to ISO 10993-11:2017.
    - Local effects after implantation testing according to ISO 10993-6:2016

  The TiUltra implants and Xeal abutments are categorized as permanent, implant devices with tissue / bone contact according to ISO 10993-1. The TiUltra implants are made of commercial pure titanium and the Xeal abutments are made of titanium vanadium alloy (ASTM F1472, ASTM 136). For surface preservation, the finished product contains a soluble salt (protective) layer composed of sodium dihydrogen phosphate dihydrate ($NaH_2PO_4 \cdot 2H_2O$) and magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$).
- **Mechanical Testing** was conducted according to ISO 14801:2016 *Dentistry — Implants — Dynamic loading test for endosseous dental implants* and the FDA Guidance Document entitled, "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*" (May 12, 2004). Following dynamic loading, an assessment of the implant-to-abutment connection platforms was conducted for wear of the anodized surface.

- **Modified surface treatment** was characterized according to the FDA Guidance Document entitled, "*Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutment*" (May 12, 2004). Additionally, testing specific to the hydrophilic surface was conducted including hydrophilicity (contact angle) measurements and conductivity (salt amount) testing.
- **An Animal Study** was conducted on the TiUltra implants and Xeal abutments and its predicates in a Yucatan mini-pig model. The comparative study conducted: clinical observations including clinical pathology, macroscopic observations, micro-CT to assess osseointegration, histomorphometry to assess osseointegration and soft tissue attachment, as well as histopathology to assess inflammatory response at 3, 6, and 13 weeks. The devices exhibited the same early and late osseointegration and/or early and late soft tissue attachment behavior.

In conclusion, the results of the non-clinical testing demonstrate that the TiUltra implants and Xeal abutments met the established performance specifications per intended use. The non-clinical testing also demonstrates that the TiUltra implants and Xeal abutments do not raise new questions of substantial equivalence when compared to the respective predicate devices.

Summary of Clinical Testing

No clinical studies submitted.

Real World Evidence (interim 18 month post market surveillance data in CE mark recognizing countries, a sponsor-investigator study in Italy, and five case studies with 3-5 month follow-ups) was provided to support the substantial equivalence. The prospective, single arm, sponsor-investigator study enrolled 61 patients. The patients received a single TiUltra implant and Xeal abutment in the posterior region of the maxilla or mandible. At the time of final prosthesis placement, on average 16.4 ± 7.3 weeks after implant placement, the patients showed successful soft tissue parameters (93%), implant survival (100%) and only one adverse event was reported due to a small dehiscence. The ability to receive the final prostheses, demonstrated there were no immediate adverse effects from the technological differences (i.e., multi-level anodization and soluble salt (protective) layer). Four patients had completed 1-year follow up radiographs and demonstrated stable bone levels further supporting the equivalent performance of the subject devices.

Conclusions

The TiUltra implants and Xeal abutments were evaluated for substantial equivalence using standard and/or comparative testing. Based on technological characteristics, non-clinical test data, and real world evidence provided in support of this 510(k), the TiUltra implants and Xeal abutments have been shown to be substantially equivalent to the predicate devices.