



August 25, 2025

Nobel Biocare AB  
Bernice Jim  
Head of RA Development Implant systems, US/CA & PLM, Strategy & EBS  
Vastra Hamngatan 1  
Goteborg, Vastra SE 411 17  
SWEDEN

Re: K243834  
Trade/Device Name: NobelZygoma TiUltra Implant system  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: DZE, NHA  
Dated: December 12, 2024  
Received: July 23, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

*Sherrill Lathrop Blitzer*

for Andrew I. Steen  
Assistant Director  
DHT1B: Division of Dental and ENT Devices  
OHT1: Office of Ophthalmic, Anesthesia,  
Respiratory, ENT, and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K243834

Device Name

NobelZygoma TiUltra Implant system

Indications for Use (Describe)

### NobelZygoma TiUltra implants

The NobelZygoma TiUltra implants are endosseous dental implants intended to be surgically placed in the zygomatic bone to support a dental prosthesis in the upper arch, in order to restore patient esthetics and chewing function. The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

### Multi-Unite Abutment Xeal Zygoma

The Multi-unit Abutments Xeal Zygoma are indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla including full arch dentures.

### NobelZygoma Multi-Unite Abutment Xeal Zygoma Screws

The NobelZygoma Multi-Unit Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

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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## 1 510(k) Summary

### 1.1 Submitter Information

Submitter: Nobel Biocare AB  
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Sweden

Submitted By: Nobel Biocare Services AG  
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Prepared By: Ana Sala Roca, Ph.D.  
Date Prepared August 22nd, 2025

## 1.2 Device Name and Classification

Proprietary name:	NobelZygoma TiUltra Implant system
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Implant
Classification Name:	Endosseous Dental Implant
Regulation Number:	21 CFR 872.3640
Device Class:	II
Primary Product Code:	DZE
Secondary Product Code:	NHA

## 1.3 Predicate Devices

### Primary Predicate Device

K152093, NobelZygoma 45° TiUnite, Nobel Biocare AB

### Reference Device:

Reference Device #1:	K161598, NobelZygoma 0° TiUnite, Nobel Biocare AB
Reference Device #2:	K222497, Zaga Zygomatic system, Southern Implants (Pty) Ltd
Reference Device #3:	K151909, Noris Medical Zygomatic Dental Implant, Noris Medical
Reference Device #4:	K050641, Brånemark System Zygoma Multi-Unit Abutment, Nobel Biocare AB
Reference Device #5:	K052885, Brånemark System Zygoma 17° Multi-unit Abutment, Nobel Biocare AB
Reference Device #6:	K161598, Multi-unit Abutment Ext Hex, Nobel Biocare AB
Reference Device #7:	K202344, NobelParallel CC TiUltra Implants, Nobel Biocare AB
Reference Device #8:	K202344, Multi-unit Abutment Xeal Conical Connection, Nobel Biocare AB

## 1.4 Device Description Summary

The Subject Device NobelZygoma TiUltra Implant system is composed of three device lines: NobelZygoma TiUltra Implants, Multi-unit Abutments Xeal Zygoma and NobelZygoma Multi-unit Abutment Xeal Zygoma Screws.

The **NobelZygoma TiUltra Implants** are endosseous dental implants surgically placed in the zygomatic bone to provide support for prosthetic devices. They are used with patients with severe bone resorption in the maxilla to provide multi-point support of the dental reconstruction. The NobelZygoma TiUltra Implants are used to support the rehabilitation of a fully or a partially edentulous maxilla. The Subject Devices are only intended for extra-maxillary placement.

The subject Implants are made from unalloyed titanium grade 4 (ASTM F67) and present a two-level anodized surface with a soluble salt (protective) layer. Two variants of the Implants are available based on the collar angulation: the NobelZygoma 0° and the NobelZygoma 45° TiUltra Implants. The NobelZygoma 0° CC TiUltra Implants feature a conical connection platform with an internal hex (size RP). The NobelZygoma 45° Ext Hex TiUltra Implants include an external hexagonal platform (size RP).

The NobelZygoma TiUltra implants are available in lengths ranging from 30 mm to 60 mm, in 2.5 mm increments. They feature a partially threaded design. The neck portion, measuring 3.6 mm from the platform, and the shaft portion which varies depending on the implant length, are unthreaded. For all implant lengths, threading consistently begins at the apex and extends 18 mm coronally.

The NobelZygoma TiUltra Implants are co-packed with an implant mount, which is attached via a pre-assembled implant mount screw to the platform of the implant.

The **Multi-unit Abutments Xeal Zygoma** are premanufactured prosthetic components intended to be connected to the compatible NobelZygoma TiUltra Implants to support the placement of a dental prosthesis.

The Multi-unit Abutment (MUA) Xeal Zygoma are made from Titanium alloy (Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium, ASTM F136) and feature a non-porous oxide layer with a soluble salt (protective) layer. The Multi-unit Abutments Xeal Zygoma are attached to the respective NobelZygoma TiUltra Implants by the compatible NobelZygoma Multi-unit Abutment Xeal Zygoma Screw.

The Multi-unit Abutment Xeal Zygoma are available in four different angulations (straight or 0°, 17°, 45° and 60°) and in different heights ranging from 3 to 9mm (2mm increase). The 45° and 60° angulations are used with the NobelZygoma 0° TiUltra implants, while

the Straight (or 0°) and 17° angulations are compatible with the NobelZygoma 45° TiUltra Implants. The 17° MUA is only available in two heights (3 and 5mm).

The Multi-unit Abutments Xeal Zygoma are provided sterile and co-packed with the respective abutment handle and NobelZygoma Multi-Unit Abutments Xeal Zygoma Screw.

The **NobelZygoma Multi-unit Abutment Xeal Zygoma Screws** are dental implant screws designed to fasten dental implant system components to a dental implant or to another component.

The subject screws are made of titanium alloy (Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium, ASTM F136) and are partially DLC-coated. They are available in different design and sizes to fit the different Multi-unit Abutments Xeal Zygoma. The Straight NobelZygoma Multi-unit Abutment Xeal Zygoma Screws are available in four sizes to fit the respective Straight Multi-Unit Abutment heights. The screws for the 45°/60° Multi-Unit Abutments and the 17° Multi-Unit Abutment are only available in one size that fits all abutment sizes.

The NobelZygoma Multi-unit Abutment Xeal Zygoma Screws are co-packed with the compatible Multi-unit Abutment Xeal Zygoma and are also available separately.

## 1.5 Intended Use/Indication for Use

**The NobelZygoma TiUltra Implants** are endosseous dental implants intended to be surgically placed in the zygomatic bone to support a dental prosthesis in the upper arch, in order to restore patient esthetics and chewing function.

The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The **Multi-unit Abutments Xeal Zygoma** are indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla including full arch dentures.

The **NobelZygoma Multi-Unit Abutment Screws** are indicated for use to secure a dental abutment or framework to a dental implant for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

## 1.6 Indications for Use Comparison

The Intended Use statement and Indications for Use statement are the same, expressed through a similar choice of words.

## 1.7 Technological Comparison

### 1.7.1 Substantial Equivalence Table - NobelZygoma 45 ° Ext Hex TiUltra Implants

	Subject Device NobelZygoma 45° Ext Hex TiUltra	Primary Predicate Device NobelZygoma 45° implants	Reference Device #2 Zaga Zygomatic system	Reference Device #3 Noris Medical Zygomatic Dental Implant	Reference Device #7 NobelParallel CC TiUltra implants	Comparison
510(k)	K243834	K152093	K222497	K151909	K202344	N/A
Manufacturer	Nobel Biocare AB	Nobel Biocare AB	Southern Implants (Pty) Ltd	Noris Medical	Nobel Biocare AB	N/A
Representative Image(s)						N/A
<b>Regulatory Aspects</b>						
Product Classification	Class II	Class II	Class II	Class II	Class II	Same as Primary Predicate.
Regulatory Number / Name	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	Same as Primary Predicate.
Product Code	DZE	DZE	DZE	DZE (NHA)	DZE	Same as Primary Predicate.
Review Panel	Dental	Dental	Dental	Dental	Dental	Same as Primary Predicate.
<b>Intended Use and Indications for Use</b>						
Intended Use	NobelZygoma TiUltra implants are endosseous implants and are integrated in the zygomatic bone (osseointegration). They are intended to be used for anchoring or supporting tooth replacements to restore chewing function.	NobelZygoma 45° implants are endosseous implants and are integrated in the zygomatic bone (osseointegration). They are intended to be used for anchoring or supporting tooth replacements to restore chewing function.	Functional and esthetic rehabilitation of the edentulous maxilla	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate	Nobel Biocare's TiUltra implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.	Same as Primary Predicate. Same as Reference Device #2 and Reference Device #3 with differences in choice of words.

	<b>Subject Device NobelZygoma 45° Ext Hex TiUltra</b>	<b>Primary Predicate Device NobelZygoma 45° implants</b>	<b>Reference Device #2 Zaga Zygomatic system</b>	<b>Reference Device #3 Noris Medical Zygomatic Dental Implant</b>	<b>Reference Device #7 NobelParallel CC TiUltra implants</b>	<b>Comparison</b>
<b>Indications for Use<sup>1</sup></b>	<p>NobelZygoma TiUltra implants are endosseous dental implants intended to be surgically placed in the zygomatic bone to support a dental prosthesis in the upper arch, in order to restore patient esthetics and chewing function.</p> <p>The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</p>	<p>NobelZygoma 45 implants are endosseous dental implants intended to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function.</p> <p>The Zygoma implants may be put into immediate function provided that stability requirements detailed in the directions for use are satisfied.</p>	<p>Straumann® Zygomatic implants are intended to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with partially or fully edentulous maxillae.</p> <p>All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</p>	<p>loading when good primary stability is achieved and with appropriate occlusal loading.</p> <p>Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.</p>	<p>NobelParallel CC TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jawbone for anchoring or supporting replacements to restore patient esthetics and chewing function.</p> <p>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 &lt;7mm length are for delayed loading only when appropriate stability has been achieved.</p>	<p>Same as Primary Predicate with minor differences in choice of words in alignment with Reference Device #1.</p> <p>Same as Reference Device #2 and Reference Device #3 with differences in choice of words.</p>
<b>Placement Method</b>	Extra-maxillary	Inside or outside the maxillary sinus	Inside or outside the maxillary sinus	Extra-maxillary	N/A	Same as Reference Device #3
<b>Technological Characteristics</b>						
<b>Device Dimensions / Design Specifications</b>						
<b>Implant Length</b> (length as per label)	30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60mm	30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50 and 52.5mm	ZAGA Round: 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60mm ZAGA Flat: 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60mm	30, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5mm	7, 8.5, 10, 11.5, 13, 15, 18mm	Similar to Primary Predicate. Same range of lengths as the Reference Device #2.

<sup>1</sup> The Intended Use and Indications for Use presented for the Subject NobelZygoma TiUltra Implant system are Device Component (Device Line) specific. The system Indications for Use is given by the Subject Implants.

	<b>Subject Device</b> NobelZygoma 45° Ext Hex TiUltra	<b>Primary Predicate Device</b> NobelZygoma 45° implants	<b>Reference Device #2</b> Zaga Zygomatic system	<b>Reference Device #3</b> Noris Medical Zygomatic Dental Implant	<b>Reference Device #7</b> NobelParallel CC TiUltra implants	<b>Comparison</b>
<b>Implant Diameter</b>	Implant neck: Ø 4.3mm Shaft: Ø 3.9mm Apical thread diameter: Ø 3.9mm	Implant neck: Ø 4.5mm Shaft: Ø 3.95mm Apical thread diameter: Ø 3.9mm	ZAGA round: 4.3 mm (coronal) taper to 3.4 mm (apical) ZAFA flat: 4.3 mm (coronal with 3.35 mm flat) taper to 3.4 mm (apical)	4.2mm  (4.2 max diameter body, 3.5 apex)	3.75, 4.3, 5.0, 5.5mm	Similar to Primary Predicate.
<b>Platform Compatibility</b>	Regular Platform (RP)	Regular Platform (RP)	4.07mm	3.75mm (4.2mm neck Ø)	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Same as Primary Predicate.
<b>Connection Type</b>	External Hex Connection	External Hex Connection	External Hex Connection	Internal conical connection (with internal hex)	Internal conical connection with hex interface	Same as Primary Predicate.
<b>Implant Platform Angulation (relative to implant axis)</b>	45° angulation at head of implant	45° angulation at head of implant	55° angulation at head of implant	(straight) 0° angulation at head of implant	(straight) 0° angulation at head of implant	Same as Primary Predicate.
<b>Angulation of compatible Abutments</b>	<i>Straight (no angulated or 0°) and 17° Zygoma Abutments</i>	<i>Straight (no angulated or 0°) and 17° Zygoma Abutments</i>	<i>Straight (no angulated or 0°)</i>	17°, 30°, 45° (extended at 52° and 60° with K210356)	<i>Straight (no angulated or 0°), 17° and 30°</i>	Same as Primary Predicate
<b>Thread Design</b>	Single helix 60° V shape thread form, length 18mm Thread pitch: 0.6mm	Single helix 60° V shape thread form, length 18mm Thread pitch: 0.6mm	Partially threaded root-form implants for placement into the zygoma. Round and machined apex with a thread pitch of 0.8mm	Tapered Screw type (length 13mm) Thread pitch: 1.295	Double lead thread with groove	Same as Primary Predicate.
<b>Implant Tip Design</b>	Tapered apex with cut out flutes	Tapered apex with cut out flutes	Tapered with cut out flutes	Double thread, double flutes	Tapered apex with cut out flutes	Same as Primary Predicate.
<b>Material</b>	Unalloyed titanium grade 4 (ASTM F67)  <i>(Implant mount &amp; implant mount screw: titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136).</i>	Unalloyed titanium grade 4 (ASTM F67)  <i>(Implant mount: unalloyed titanium grade 1 (ASTM F67) &amp; Implant mount screw: titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136. DLC coating.)</i>	Unalloyed titanium grade 4 (ASTM F67), and UTS ≥ 900Mpa (cold-worked)	Titanium alloy Ti 6Al 4V ELI	Unalloyed titanium grade 4 (ASTM F67)	Same materials as Primary Predicate.
<b>Surface Treatment</b>	Anodic oxidation (anodization)	Anodic oxidation (anodization)	Grit-blasted	-machined surface at the coronal/shaft region -resorbable blast media (distal Surface/threaded apex)	Anodic oxidation (anodization)	The Subject Device, the Primary Predicate and the Reference Device #7 present an anodic anodized surface. The Subject Device at the collar/shaft present the same

	Subject Device NobelZygoma 45° Ext Hex TiUltra	Primary Predicate Device NobelZygoma 45° implants	Reference Device #2 Zaga Zygomatic system	Reference Device #3 Noris Medical Zygomatic Dental Implant	Reference Device #7 NobelParallel CC TiUltra implants	Comparison
						Xeal anodized surface as the Level 0 (collar) of the Reference Device #7. The Reference Device #3 presents a machined surface at the collar/shaft.
<b>Surface Topography</b>	<p>TiUltra - two level surface:</p> <p>Level 1 (shaft and coronal part):</p> <ul style="list-style-type: none"> <li>- Xeal yellow anodization</li> <li>- Sa (area roughness) = 0.5±0.3µm</li> <li>- Thickness = 0.17±0.01µm</li> </ul> <p>Level 2 (threaded apex):</p> <ul style="list-style-type: none"> <li>- Spark-anodized</li> <li>- Sa = 1.5 ± 0.4µm</li> <li>- Thickness = 12.0±1.2µm</li> </ul>	<p>TiUnite – single level surface:</p> <ul style="list-style-type: none"> <li>- Sa = 1.2 ± 0.5µm</li> <li>- Thickness = 12.5 ± 2.5µm</li> </ul>	-----	<p>Collar/Shaft (Level 1) - surface roughness total average:</p> <ul style="list-style-type: none"> <li>- Sa (area roughness) = ca. 0.27µm</li> </ul>	<p>TiUltra – three level surface:</p> <p>Level 0 (collar):</p> <ul style="list-style-type: none"> <li>- Xeal yellow anodization</li> <li>- Sa=0.5±0.3µm</li> <li>- Thickness = 0.17±0.01µm</li> </ul> <p>Level 1 (transition):</p> <ul style="list-style-type: none"> <li>- Spark-anodized</li> <li>- Roughness: Sa=0.8±0.3µm</li> <li>- Thickness: 7.5 ± 0.3µm</li> </ul> <p>Level 2 (body/apex):</p> <ul style="list-style-type: none"> <li>- Spark-anodized</li> <li>- Sa = 1.5 ± 0.4µm</li> <li>- Thickness = 12.0 ± 1.2µm</li> </ul>	The surface roughness of the Subject Device at Level 1 (collar/shaft) is between the surface roughness of the Primary Predicate and the Reference Device #3. Same Surface technology as Reference Device #7 but featuring two levels instead of three levels.
<b>Surface Preservation</b>	<p>Soluble salt (protective) layer:</p> <p>Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt on apex, shaft, and collar (excluding connection/ platform).</p> <p>Concentration: 0.1-200µg/cm<sup>2</sup></p>	None	None	None	<p>Soluble salt (protective) layer:</p> <p>Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt on apex, shaft, and collar (excluding connection/ platform).</p> <p>Concentration: 0.1-200µg/cm<sup>2</sup></p>	Same soluble salt (protective layer) as Reference Device #7.
<b>Packaging, Sterility, Shelf-Life, Anatomical Location and Use</b>						
<b>Sterile at supply</b>	Yes (Gamma sterilization; SAL 10 <sup>-6</sup> )	Yes (Gamma sterilization; SAL 10 <sup>-6</sup> )	Yes (Gamma sterilization)	Yes (Gamma sterilization)	Yes (Gamma sterilization; SAL 10 <sup>-6</sup> )	Same as Primary Predicate.
<b>Initial processing needed</b>	No	No	No	No	No	Same as Primary Predicate.

	<b>Subject Device</b> NobelZygoma 45° Ext Hex TiUltra	<b>Primary Predicate Device</b> NobelZygoma 45° implants	<b>Reference Device #2</b> Zaga Zygomatic system	<b>Reference Device #3</b> Noris Medical Zygomatic Dental Implant	<b>Reference Device #7</b> NobelParallel CC TiUltra implants	<b>Comparison</b>
<b>Reusability</b>	Single-use	Single-use	Single-use	Single-use	Single-use	Same as Primary Predicate.
<b>Shelf-life</b>	5 years	5 years	-----	-----	5 years	Same as Primary Predicate.
<b>Packaging</b>	Titanium implant sleeve placed in a polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lid (sterile barrier). The blister is then placed into a cardboard box (protective packaging).  (single-sterile barrier) (co-packed with preassembled implant mount/implant mount screw)	Titanium implant sleeve casing inside a copolyester vial with a high density polyethylene (HDPE) outer vial cap (1 <sup>st</sup> sterile barrier). The vial is placed in a polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lead (2 <sup>nd</sup> sterile barrier), which is then inserted into a cardboard box.  (double-sterile barrier) (co-packed with preassembled implant mount/ implant mount screw and with cover screw)	-----	-----	Titanium Implant sleeve placed into a copolyester vial with high density polyethylene (HDPE) outer cap (1 <sup>st</sup> sterile barrier). The vial is placed in a polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lead (2 <sup>nd</sup> sterile barrier), which is then inserted into a cardboard box.  (double-sterile barrier)	Subject devices present a single-sterile barrier similar to Nobel Biocare N1 Implants (K211109).
<b>Duration of use</b>	Permanent implantable	Permanent implantable	Permanent implantable	Permanent implantable	Permanent implantable	Same as Primary Predicate.
<b>Anatomical location</b>	Oral cavity - upper jaw arch, integrated in the zygomatic bone	Oral cavity - upper jaw arch, integrated in the zygomatic bone	Oral cavity - upper jaw arch, integrated in the zygomatic bone	Oral cavity - upper jaw arch, integrated in the zygomatic bone	Oral cavity – upper and/or lower jaw (maxilla and/or mandible)	Same as Primary Predicate.

## 1.7.2 Substantial Equivalence Table - NobelZygoma 0 ° CC TiUltra Implants

	Subject Device NobelZygoma 0° CC TiUltra	Reference Device #1 NobelZygoma 0° TiUnite	Reference Device #2 Zaga Zygomatic system	Reference Device #3 Noris Medical Zygomatic Dental Implant	Reference Device #7 NobelParallel CC TiUltra implants	Comparison
510(k)	K243834	K161598	K222497	K151909	K202344	N/A
Manufacturer	Nobel Biocare AB	Nobel Biocare AB	Southern Implants (Pty) Ltd	Noris Medical	Nobel Biocare AB	N/A
Representative Image(s)						N/A
<b>Regulatory Aspects</b>						
Product Classification	Class II	Class II	Class II	Class II	Class II	Same as Reference Device #1.
Regulatory Number / Name	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	Same as Reference Device #1.
Primary Product Code	DZE	DZE	DZE	DZE	DZE	Same as Reference Device #1.
Review Panel	Dental	Dental	Dental	Dental	Dental	Same as Reference Device #1.
<b>Intended Use and Indications for Use</b>						
Intended Use	NobelZygoma TiUltra implants are endosseous implants and are integrated in the zygomatic bone (osseointegration). They are intended to be used for anchoring or supporting tooth replacements to restore chewing function.	NobelZygoma™ 0° implants are endosseous implants and are integrated in the zygomatic bone (osseointegration). They are intended to be used for anchoring or supporting tooth replacements to restore chewing function.	Functional and esthetic rehabilitation of the edentulous maxilla	Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary	Nobel Biocare's TiUltra implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.	Same as Reference Device #1. Same as Reference Device #2 and Reference Device #3 with differences in choice of words.

	Subject Device NobelZygoma 0° CC TiUltra	Reference Device #1 NobelZygoma 0° TiUnite	Reference Device #2 Zaga Zygomatic system	Reference Device #3 Noris Medical Zygomatic Dental Implant	Reference Device #7 NobelParallel CC TiUltra implants	Comparison
<b>Indications for Use<sup>2</sup></b>	<p>NobelZygoma TiUltra implants are endosseous dental implants intended to be surgically placed in the zygomatic bone to support a dental prosthesis in the upper arch, such as artificial teeth, in order to restore patient esthetics and chewing function.</p> <p>The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</p>	<p>NobelZygoma™ 0° implants are endosseous dental implants indicated to be surgically placed in the bone of the upper jaw arch to provide support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function.</p> <p>The NobelZygoma Implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</p>	<p>Straumann Zygomatic implants are intended to be implanted in the upper jaw arch to provide support for fixed dental prostheses in patients with partially or fully edentulous maxillae.</p> <p>All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.</p>	<p>stability is achieved and with appropriate occlusal loading.</p> <p>Noris Medical Zygomatic Dental Implant System is intended to be implanted in the upper jaw arch to provide support for fixed or removable prosthetic devices in patients with partially or fully edentulous maxillae.</p>	<p>NobelParallel CC TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jawbone for anchoring or supporting replacements to restore patient esthetics and chewing function.</p> <p>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.</p> <p>Implants with &lt;7mm length are for delayed loading only when appropriate stability has been achieved.</p>	<p>Same as Reference #1, Reference Device #2 and Reference Device #3 with differences in choice of words.</p>
<b>Placement Method</b>	Extra-maxillary	Inside or outside the maxillary sinus	Inside or outside the maxillary sinus	Extra-maxillary	N/A	Same as Reference Device #3
<b>Technological Characteristics</b>						
<b>Device Dimensions / Design Specifications</b>						
<b>Implant Length (length as per label)</b>	30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60mm	30, 35, 37.5, 40, 42.5, 45, 47.5 and 50mm	ZAGA Round: 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60mm	30, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5mm	7, 8.5, 10, 11.5, 13, 15, 18mm	Same range of lengths as the Reference Device #2.

<sup>2</sup> The Intended Use and Indications for Use presented for the Subject NobelZygoma TiUltra Implant system are Device Component (or Device Line) specific. The system Indications for Use is given by the Subject Implants.

	Subject Device NobelZygoma 0° CC TiUltra	Reference Device #1 NobelZygoma 0° TiUnite	Reference Device #2 Zaga Zygomatic system	Reference Device #3 Noris Medical Zygomatic Dental Implant	Reference Device #7 NobelParallel CC TiUltra implants	Comparison
			ZAGA Flat: 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60mm			
<b>Implant Diameter</b>	Implant neck: Ø 4.3mm Shaft: Ø 3.9mm Apical thread Diameter: Ø 3.9mm	Implant neck: Ø 4.5mm Shaft: Ø 4.3mm diameter Apical thread Diameter: Ø 4.97mm	ZAGA round: 4.3 mm (coronal) taper to 3.4 mm (apical) ZAFA flat: 4.3 mm (coronal with 3.35 mm flat) taper to 3.4 mm (apical)	4.2mm  (4.2 max diameter body, 3.5 apex)	3.75, 4.3, 5.0, 5.5mm	Similar to Reference Device #1 and to Primary Predicate device (Section 1.9.1).
<b>Platform Compatibility</b>	Regular Platform (RP)	Regular Platform (RP)	4.07mm	3.75mm (4.2mm neck Ø)	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Same as Reference Device #1
<b>Connection Type</b>	Internal conical Connection (with internal hex)	External Hex Connection	External Hex Connection	Internal conical connection (with internal hex)	Internal conical Connection (with internal hex)	Both the Subject Device and the Reference Device #3 present an internal conical connection (with internal hex). Same connection as Reference Device #7
<b>Implant Angulation</b>	(straight) 0° angulation at head of implant	(straight) 0° angulation at head of implant	55° angulation at head of implant	(straight) 0° angulation at head of implant	(straight) 0° angulation at head of implant	Same as Reference Device #1
<b>Angulation compatible Abutments</b>	45° 60°	45° 60°	Straight (no angulated or 0°)	17°, 30°, 45° (extended at 52° and 60° with K210356)	straight (no angulation or 0°) 17° 30°	Same as Reference Device #1
<b>Thread Design</b>	Single helix 60° V shape thread form, length 18mm Thread pitch: 0.6mm	Single helix 60° V shape thread form, length 18mm Thread pitch: 0.6mm	Partially threaded root-form implants for placement into the zygoma. Round apex with a thread pitch of 0.8mm	Tapered Screw type (length 13mm) Thread pitch: 1.295	Double lead thread with groove	Same as Reference Device #1.
<b>Implant Tip Design</b>	Tapered apex with cut out flutes	Tapered apex with cut out flutes	Tapered with cut out flutes	Double thread, double flutes	Tapered apex with cut out flutes	Same as Reference Device #1.
<b>Material</b>	Unalloyed titanium grade 4 (ASTM F67)  <i>(Implant mount &amp; implant mount screw: titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) according to ASTM F136).</i>	Unalloyed titanium grade 4 (ASTM F67)  <i>(no implant mount)</i>	Unalloyed titanium grade 4 (ASTM F67), and UTS ≥ 900Mpa (cold-worked)	Titanium alloy Ti 6Al 4V ELI	Unalloyed titanium grade 4 (ASTM F67)	Implant material is the same as Reference Device #1. Implant mount & implant mount screw same materials as the Primary Predicate (see section 1.7.1).
<b>Surface Treatment</b>	Anodic oxidation (anodization)	Anodic oxidation (anodization)	Grit-blasted	-machined surface at the coronal/shaft region -resorbable blast media (distal Surface/threaded apex)	Anodic oxidation (anodization)	The Subject Device, the Primary Predicate and the Reference Device #1

	Subject Device NobelZygoma 0° CC TiUltra	Reference Device #1 NobelZygoma 0° TiUnite	Reference Device #2 Zaga Zygomatic system	Reference Device #3 Noris Medical Zygomatic Dental Implant	Reference Device #7 NobelParallel CC TiUltra implants	Comparison
						<p>present an anodic anodized surface.</p> <p>The Subject Device at the collar/shaft present the same Xeal anodized surface as the Level 0 (collar) of the Reference Device #7.</p> <p>The Reference Device #3 presents a machined surface at the collar/shaft.</p>
<b>Surface Topography</b>	<p>TiUltra - two level surface:</p> <p>Level 1 (shaft and coronal part):</p> <ul style="list-style-type: none"> <li>- Xeal yellow anodization</li> <li>- Sa (area roughness) = <math>0.5 \pm 0.3 \mu\text{m}</math></li> <li>- Thickness = <math>0.17 \pm 0.01 \mu\text{m}</math></li> </ul> <p>Level 2 (threaded apex):</p> <ul style="list-style-type: none"> <li>- Spark-anodized</li> <li>- Sa = <math>1.5 \pm 0.4 \mu\text{m}</math></li> <li>- Thickness = <math>12.0 \pm 1.2 \mu\text{m}</math></li> </ul>	<p>TiUnite – Single level surface:</p> <ul style="list-style-type: none"> <li>- Sa = <math>1.2 \pm 0.5 \mu\text{m}</math></li> <li>- Thickness = <math>12.5 \pm 2.5 \mu\text{m}</math></li> </ul>	-----	<p>Collar/Shaft (Level 1) - surface roughness total average:</p> <ul style="list-style-type: none"> <li>- Sa (area roughness) = ca. <math>0.27 \mu\text{m}</math></li> </ul>	<p>TiUltra – Three level surface:</p> <p>Level 0 (collar):</p> <ul style="list-style-type: none"> <li>- Xeal yellow anodization</li> <li>- Sa = <math>0.5 \pm 0.3 \mu\text{m}</math></li> <li>- Thickness = <math>0.17 \pm 0.01 \mu\text{m}</math></li> </ul> <p>Level 1 (transition):</p> <ul style="list-style-type: none"> <li>- Spark-anodized</li> <li>- Roughness: Sa = <math>0.8 \pm 0.3 \mu\text{m}</math></li> <li>- Thickness: <math>7.5 \pm 0.3 \mu\text{m}</math></li> </ul> <p>Level 2 (body/apex):</p> <ul style="list-style-type: none"> <li>- Spark-anodized</li> <li>- Sa = <math>1.5 \pm 0.4 \mu\text{m}</math></li> <li>- Thickness = <math>12.0 \pm 1.2 \mu\text{m}</math></li> </ul>	<p>The surface roughness of the Subject Device at Level 1 (collar/shaft) is between the surface roughness of the Reference Device #1 and the Reference Device #3. Same Surface technology as Reference Device #7 but featuring two levels instead of three levels.</p>
<b>Surface Preservation</b>	<p>Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt on apex, shaft, and collar (excl. connection/ platform).</p> <p>Concentration: <math>0.1-200 \mu\text{g}/\text{cm}^2</math></p>	None	None	None	<p>Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt on apex, shaft, and collar (excl. connection/ platform).</p> <p>Concentration: <math>0.1-200 \mu\text{g}/\text{cm}^2</math></p>	<p>Same soluble salt (protective layer) as Reference Device #7.</p>

	Subject Device NobelZygoma 0° CC TiUltra	Reference Device #1 NobelZygoma 0° TiUnite	Reference Device #2 Zaga Zygomatic system	Reference Device #3 Noris Medical Zygomatic Dental Implant	Reference Device #7 NobelParallel CC TiUltra implants	Comparison
<b>Packaging, Sterility, Shelf-Life, Anatomical Location and Use</b>						
<b>Sterile at supply</b>	Yes (Gamma sterilization; SAL 10 <sup>-6</sup> )	Yes (Gamma sterilization; SAL 10 <sup>-6</sup> )	Yes (Gamma sterilization)	Yes (Gamma sterilization)	Yes (Gamma sterilization; SAL 10 <sup>-6</sup> )	Same as Reference Device #1.
<b>Initial processing needed</b>	No	No	No	No	No	Same as Reference Device #1.
<b>Reusability</b>	Single-use	Single-use	Single-use	Single-use	Single-use	Same as Reference Device #1.
<b>Shelf-life</b>	5 years	5 years	-----	-----	5 years	Same as Reference Device #1.
<b>Packaging</b>	Titanium implant sleeve placed in a polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lid (sterile barrier). The blister is then placed into a cardboard box (protective packaging).  (single-sterile barrier)  <i>(co-packed with preassembled implant mount/ implant mount screw)</i>	Titanium implant sleeve with a PEEK sleeve cap placed inside a copolyester vial with a high-density polyethylene (HDPE) outer vial cap (1 <sup>st</sup> sterile barrier). The vial is placed in a polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lid (2 <sup>nd</sup> sterile barrier), which is then inserted into a cardboard box. (K183069) <i>(double-sterile barrier) (co-packed with cover screw)</i>	-----	-----	Titanium Implant sleeve placed into a copolyester vial with high-density polyethylene (HDPE) vial cap (1 <sup>st</sup> sterile barrier). The vial is placed in a polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lid (2 <sup>nd</sup> sterile barrier), which is then inserted into a cardboard box.  (double-sterile barrier)	Subject Devices present a single-sterile barrier similar to cleared Nobel Biocare N1 Implants (K211109). The differences when compared to Reference Device #1 do not raise different questions of safety and effectiveness.
<b>Duration of use</b>	Permanent implantable	Permanent implantable	Permanent implantable	Permanent implantable	Permanent implantable	Same as Reference Device #1.
<b>Anatomical location</b>	Oral cavity - upper jaw arch, integrated in the zygomatic bone	Oral cavity - upper jaw arch, integrated in the zygomatic bone	Oral cavity - upper jaw arch, integrated in the zygomatic bone	Oral cavity - upper jaw arch, integrated in the zygomatic bone	Oral cavity – upper and/or lower jaw (maxilla and/or mandible)	Same as Reference Device #1.

### 1.7.3 Substantial Equivalence Table – Straight and 17° Multi-unit Abutments (MUAs) Xeal Zygoma and respective NobelZygoma Multi-unit Abutment Xeal Zygoma Screws

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma Ext Hex (Straight and 17°) (Screw: straight and 17° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws)	<b>Reference Device#4</b> Brånemark System Zygoma Multi-Unit Abutment (Straight) (Screw: Screw for Zygoma MUA)	<b>Reference Device #5</b> Brånemark System Zygoma Multi-Unit Abutment (17°) (Screw: Brånemark System Zygoma Angled Multi-unit Abutment Screw)	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal™ Conical Connection	<b>Comparison</b>
<b>510(k)</b>	K243834	K050641	K052885	K202344	N/A
<b>Manufacturer</b>	Nobel Biocare AB	Nobel Biocare AB	Nobel Biocare AB	Nobel Biocare AB	N/A
<b>Representative Image(s)</b>	Straight / 0° 	Straight / 0° 	—	 Representative Images of Multi-unit Abutment (MUA) Xeal™ Conical Connection  (straight / 0°, 17° and 30°)	N/A
	17° 	—	17° 		
<b>Regulatory Aspects - Multi-Unit Abutments and Screws</b>					
<b>Product Classification (MUAs and Screws)</b>	Class II	Class II	Class II	Class II	Same as respective predicate and reference devices: Reference Device#4 and Reference Device#5.
<b>Regulatory Number / Name</b>	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 872.3630 Endosseous dental implant abutment.	Same as respective predicate and reference devices: Reference Device#4 and Reference Device#5.
<b>Primary Product Code</b>	NHA	NHA	NHA	NHA	Same as respective predicate and reference

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma Ext Hex (Straight and 17°) (Screw: straight and 17° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws)	<b>Reference Device#4</b> Brånemark System Zygoma Multi-Unit Abutment (Straight) (Screw: Screw for Zygoma MUA)	<b>Reference Device #5</b> Brånemark System Zygoma Multi-Unit Abutment (17°) (Screw: Brånemark System Zygoma Angled Multi-unit Abutment Screw)	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal™ Conical Connection	<b>Comparison</b>
					devices: Reference Device#4 and Reference Device#5.
<b>Review Panel</b>	Dental	Dental	Dental	Dental	Same as respective predicate and reference devices: Reference Device#4 and Reference Device#5.
<b>Intended Use and Indications for Use - Multi-Unit Abutments</b>					
<b>Intended Use<sup>3</sup></b>	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Same as respective predicate and reference devices: Reference Device#4 and Reference Device#5.
<b>Indications for Use<sup>3</sup></b>	Indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla including full arch dentures.	Indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla including full arch dentures.	Indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla including full arch dentures.	Indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla or mandible including full arch dentures.	Same as Reference Device#4 and Reference Device#5.
<b>Intended Use and Indications for Use - Screws</b>					
<b>Intended Use<sup>3</sup></b>	Intended for use to fasten dental implant system components to a dental implant or to another component.	Intended for use to fasten dental implant system components to a dental implant or to another component.	Intended for use to fasten dental implant system components to a dental implant or to another component.	N/A	Same as Reference Devices #4 and #5.

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma Ext Hex (Straight and 17°) (Screw: straight and 17° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws)	<b>Reference Device#4</b> Brånemark System Zygoma Multi-Unit Abutment (Straight) (Screw: Screw for Zygoma MUA)	<b>Reference Device #5</b> Brånemark System Zygoma Multi-Unit Abutment (17°) (Screw: Brånemark System Zygoma Angled Multi-unit Abutment Screw)	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal™ Conical Connection	<b>Comparison</b>
<b>Indications for Use<sup>3</sup></b>	The NobelZygoma Multi-Unit Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.	The NobelZygoma Multi-Unit Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.	The NobelZygoma Multi-Unit Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.	N/A	Same as Reference Devices #4 and #5.
<b>Technological Characteristics Multi-Unit Abutments and Screws</b>					
<b>Device Dimensions/ Design Specifications Multi-Unit Abutments and Screws</b>					
<b>Abutment Height</b> (A – distance along the axis of the prosthetic screw /gingival height) (B – distance along the axis of the clinical screw)	<u>Straight MUA:</u> A/B: ca. 3, 5, 7, and 9mm <u>17° MUA:</u> A: ca. 3 and 5mm B: ca. 4 and 6.3mm	A / B: ca. 3mm and 5mm	B: ca. 2mm and 3mm A: ca. 1 and 2mm	<u>Straight MUA:</u> A/B: ca. 1.5, 2.5, 3.5, 4.5mm <u>17° MUA:</u> A: ca. 1.5 and 2.5mm B: ca. 2.5, 3.5 mm	Similar to respective predicate and reference devices: Reference Device#4 and Reference Device#5.
<b>Multi-unit Abutment width</b> (at the prosthetic platform)	4.8mm	4.8mm	4.8mm	4.8mm	Same as respective predicate and reference devices: Reference Device#4 and Reference Device#5.
<b>Screw Length</b> (total length)	<u>Straight screw:</u> 6.525, 8.525, 10.525, 12.625mm <u>17° screw:</u> 3.4mm	6.55mm	3.4mm	N/A	Similar to Reference Device #4 and same as Reference Device #5.
<b>Screw Shaft Diameter</b> (Minimum-nominal)	<u>Straight screw:</u> 1.485mm <u>17° screw:</u> 1.6 mm	1.485 mm	1.6mm	N/A	Same as respective predicate and reference devices: Reference

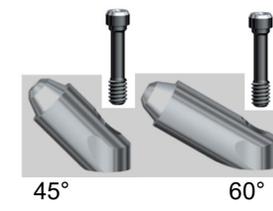
<sup>3</sup> The Intended Use and Indications for Use presented for the Subject NobelZygoma TiUltra Implant system are Device Component (Device Line) specific. The system Indications for Use is given by the Subject Implants.

	<b>Subject Devices</b> Multi-unit Abutment Zeal Zygoma Ext Hex (Straight and 17°) (Screw: straight and 17° Nobel Zygoma Multi-unit Abutment Zeal Zygoma Screws)	<b>Reference Device#4</b> Brånemark System Zygoma Multi-Unit Abutment (Straight) (Screw: Screw for Zygoma MUA)	<b>Reference Device #5</b> Brånemark System Zygoma Multi-Unit Abutment (17°) (Screw: Brånemark System Zygoma Angled Multi-unit Abutment Screw)	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Zeal™ Conical Connection	<b>Comparison</b>
					Device#4 and Reference Device#5.
<b>Multi-unit Abutment Platform Compatibility</b>	Regular Platform (RP)	Regular Platform (RP)	Regular Platform (RP)	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Same as respective predicate and reference devices: Reference Device#4 and Reference Device#5.
<b>Multi-unit Abutment Connection Type</b>	External Hex connection	External Hex connection	External Hex connection	Conical Connection	Same as respective predicate and reference devices: Reference Device#4 and Reference Device#5.
<b>Screws-Screwdriver Interface</b>	Straight screw: MUA driver 17° screw: Unigrip	MUA driver	Unigrip	N/A	Same as respective predicate and reference devices: Reference Device #4 and Reference Device #5.
<b>Multi-unit Abutment Angulation</b>	straight (0°) 17° angulated (used with compatible 45° Nobel Biocare zygomatic implants)	straight (0°) (used with compatible 45° Nobel Biocare zygomatic implants)	17° angulated (used with compatible 45° Nobel Biocare zygomatic implants)	Straight (0°) 17° angulated 30° angulated	Same as respective predicate and reference devices: Reference Device #4 and Reference Device #5.
<b>Multi-unit Abutment and Screw Material</b>	MUAs and Screws: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) (ASTM F136)	MUA: pure titanium according to ASTM F67. Screw: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) (ASTM F136)	MUAs and Screw: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) (ASTM F136)	Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) (ASTM F136)	The Subject Abutments are made of Titanium Alloy, same materials used in Reference Device #5.
<b>Multi-unit Abutment and Screw Surface Treatment</b>	MUAs: Anodization Screws: partial DLC coated (screw body)	MUA: no treatment (machined) Screws: partial DLC coated (screw body)	MUA: no treatment (machined) Screws: partial DLC coated (screw body)	MUA: Anodization	Same as Reference Device #8.

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma Ext Hex (Straight and 17°) (Screw: straight and 17° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws)	<b>Reference Device#4</b> Brånemark System Zygoma Multi-Unit Abutment (Straight) (Screw: Screw for Zygoma MUA)	<b>Reference Device #5</b> Brånemark System Zygoma Multi-Unit Abutment (17°) (Screw: Brånemark System Zygoma Angled Multi-unit Abutment Screw)	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal™ Conical Connection	<b>Comparison</b>
<b>Multi-unit Abutment Surface Topography</b>	Xeal – Single level surface: Sa (area roughness) <0.8 µm	Machined Ra < 3.2 µm	Machined Ra < 3.2 µm	Xeal – Single level surface: Sa (area roughness) <0.8 µm	Same as Reference Device #8.
<b>Multi-unit Abutment Hydrophilic surface treatment</b>	Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt on whole abutment surface. Salt concentration: 0.01 – 2.35µg/mm <sup>2</sup>	None	None	Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt on whole abutment surface. Salt concentration: 0.01– 2.35 µg/mm <sup>2</sup>	Same soluble salt (protective layer) as Reference Device #8.
<b>Packaging, Sterility and Shelf-life - Multi-unit Abutments</b>					
<b>Multi-unit Abutment Packaging</b>	Polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lid forming a single sterile barrier system.  <i>co-packed with screws and abutment holder</i>	Polyethylene terephthalate glycol (PETG) blister sealed with a medical Tyvek lid forming a single sterile barrier system)  <i>co-packed with screws and abutment holder</i>	Polyethylene terephthalate glycol (PETG) blister sealed with a medical Tyvek lid forming a single sterile barrier system)  <i>co-packed with screws and abutment holder</i>	Polyethylene terephthalate glycol (PETG) blister sealed with a medical Tyvek lid forming a single sterile barrier system).	Same as Reference Device #4 and Reference Device #5.
<b>Multi-unit Abutments Sterility at supply</b>	Yes (Gamma sterilization SAL 10-6)	Yes (Gamma sterilization SAL 10-6)	Yes (Gamma sterilization SAL 10-6)	Yes (Gamma sterilization SAL 10-6)	Same as Reference Device #4 and Reference Device #5.
<b>Multi-unit Abutments Shelf life</b>	5 years	5 years	5 years	5 years	Same as Reference Device #4 and Reference Device #5.
<b>Multi-unit Abutments Initial processing needed</b>	No	No	No	No	Same as Reference Device#4 and Reference Device#5.

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma Ext Hex (Straight and 17°) (Screw: straight and 17° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws)	<b>Reference Device#4</b> Brånemark System Zygoma Multi-Unit Abutment (Straight) (Screw: Screw for Zygoma MUA)	<b>Reference Device #5</b> Brånemark System Zygoma Multi-Unit Abutment (17°) (Screw: Brånemark System Zygoma Angled Multi-unit Abutment Screw)	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal™ Conical Connection	<b>Comparison</b>
<b>Packaging, Sterility and Shelf-life – Screws (as standalone)</b>					
<b>Screws Packaging</b>	Polyethylene terephthalate glycol (PETG) blister with a Tyvek lid forming a single sterile barrier.	N/A (only available co-packed with MUA)	Polyethylene terephthalate glycol (PETG) blister with a Tyvek lid	N/A	Same as respective Multi-Unit Abutment predicate and reference devices (Reference Device #4 and #5).
<b>Screws Sterile at supply</b>	Yes (Gamma sterilization SAL 10 <sup>-6</sup> )	N/A (see packaging, sterility, and shelf-life for MUAs)	No (see packaging, sterility, and shelf-life for MUAs)	N/A	Same as respective Multi-Unit Abutment predicate and reference devices (Reference Device #4 and #5).
<b>Screws Shelf life</b>	5 years	N/A (see packaging, sterility, and shelf-life for MUAs)	N/A (non-sterile device) (see packaging, sterility, and shelf-life for MUAs)	N/A	Same as respective Multi-Unit Abutment Reference Devices #4 and #5.
<b>Screws Initial processing needed</b>	No	N/A (see packaging, sterility, and shelf-life for MUAs)	Yes (see packaging, sterility, and shelf-life for MUAs)	N/A	Subject Devices are single-use and provided sterile. No reprocessing submitted as part of this 510(k).
<b>Anatomical location and Use - Multi-unit Abutments and Screws</b>					
<b>Reusability</b>	Single use	Single use	Single use	Single use	Same as Reference Device #4 and Reference Device #5.
<b>Duration of use</b>	Permanent implantable	Permanent implantable	Permanent implantable	Permanent implantable	Same as Reference Device #4 and Reference Device #5.
<b>Anatomical location</b>	Oral cavity - upper jaw	Oral cavity - upper jaw	Oral cavity - upper jaw	Oral cavity – upper or lower jaw	Same as Reference Device #4 and Reference Device #5.

### 1.7.4 Substantial Equivalence Table - 45° and 60° Multi-unit Abutments (MUAs) Xeal Zygoma and respective 45°/60° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma CC (45° and 60°) <u>Screw</u> : 45°/60° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws	<b>Reference Device #6</b> Multi-unit Abutment Ext Hex (45° and 60°) <u>Screw</u> : NobelZygoma 0° Angled Multi-Unit Abutment Screw	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal Conical Connection	<b>Comparison</b>
<b>510(k)</b>	<b>K243834</b>	<b>K161598</b>	<b>K202344</b>	N/A
<b>Manufacturer</b>	Nobel Biocare AB	Nobel Biocare AB	Nobel Biocare AB	N/A
<b>Representative Image(s)</b>	 <p>45°                      60°</p>	 <p>45°                      60°</p>	 <p>(Straight, 17°/30°)</p>	N/A
<b>Regulatory Aspects - Multi-Unit Abutments and Screws</b>				
<b>Product Classification</b>	Class II	Class II	Class II	Same as Reference #6.
<b>Regulatory Number / Name</b>	21 CFR 872.3630 Endosseous dental implant abutment	21 CFR 872.3630 Endosseous dental implant abutment	21 CFR 872.3630 Endosseous dental implant abutment	Same as Reference #6.
<b>Primary Product Code</b>	NHA	NHA	NHA	Same as Reference #6.
<b>Review Panel</b>	Dental	Dental	Dental	Same as Reference #6.

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma CC (45° and 60°) Screw: 45°/60° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws	<b>Reference Device #6</b> Multi-unit Abutment Ext Hex (45° and 60°) Screw: NobelZygoma 0° Angled Multi-Unit Abutment Screw	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal Conical Connection	<b>Comparison</b>
<b>Intended Use and Indications for Use - Multi-Unit Abutments</b>				
<b>Intended Use<sup>4</sup></b>	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis	Same as Reference Device #6.
<b>Indications for Use<sup>4</sup></b>	Indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla including full arch dentures.	Indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla including full arch dentures	Indicated to support the placement of multiple unit, screw-retained prosthetic restorations in the maxilla or mandible including full arch dentures.	Same as Reference Device #6.
<b>Intended Use and Indications for Use - Screws</b>				
<b>Intended Use<sup>4</sup></b>	Intended for use to fasten dental implant system components to a dental implant or to another component.	Intended for use to fasten dental implant system components to a dental implant or to another component.	N/A	Same as Reference Device #6.
<b>Indications for Use<sup>4</sup></b>	The NobelZygoma Multi-Unit Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.	The NobelZygoma Multi-Unit Abutment Screws are indicated for use to secure a dental abutment or framework to a dental implant for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.	N/A	Same as Reference Device #6.
<b>Technological Characteristics Multi-Unit Abutments and Screws</b>				
<b>Device Dimensions/ Design Specifications Multi-Unit Abutments and Screws</b>				
<b>Multi-unit Abutment Height</b> <i>(A – distance along the axis of the prosthetic screw /gingival height)</i>	<b>45° MUA:</b> A: ca. 3,5,7,9mm B: ca. 5.1, 6.8, 8.2, 9.6mm	<b>45° MUA:</b> A: ca. 3.7, 6.5, 9.4mm B: ca. 6, 8 and 10mm	A: ca. 1.5 and 2.5mm B: ca. 3.5 and 4.5mm	Within range of Reference Device #6 heights.

<sup>4</sup> The Intended Use and Indications for Use presented for the Subject NobelZygoma TiUltra Implant system are Device Component (or Device Line) specific. The system Indications for Use is given by the Subject Implants.

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma CC (45° and 60°) Screw: 45°/60° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws	<b>Reference Device #6</b> Multi-unit Abutment Ext Hex (45° and 60°) Screw: NobelZygoma 0° Angled Multi-Unit Abutment Screw	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal Conical Connection	<b>Comparison</b>
<i>(B – distance along the axis of the clinical screw)</i>	<b>60° MUA:</b> A: ca. 3,5,7,9mm B: ca. 5.5, 6.5, 7.5, 8.5mm	<b>60° MUA:</b> A: ca. 4.2 and 8.2mm B: ca. 6 and 8mm		
<b>Multi-unit Abutment width</b> <i>(at the prosthetic platform)</i>	4.8mm	4.8mm	4.8mm	Same as Reference Device #6.
<b>Screw Length</b> <i>(total length)</i>	8.625 mm	9.825mm	N/A	Within range of Reference Device #6.
<b>Screw Shaft Diameter</b>	1.475 mm	1.475 mm	N/A	Same as Reference Device #6.
<b>Multi-unit Abutment Platform Compatibility</b>	Regular Platform (RP)	Regular Platform (RP)	Narrow Platforme (NP) Regular Platform (RP) Wide Platform (WP)	Same as ReferenceDevice #6.
<b>Multi-unit Abutment Connection Type</b>	Conical Connection (internal hex)	External Hex Connection	Conical Connection (internal hex)	Same as Reference Device #8.
<b>Screws- Screwdriver Interface</b>	Unigrip	Unigrip	N/A	Same as ReferenceDevice #6.
<b>Multi-unit Abutment Angulation</b>	45° and 60° <i>(used with compatible 0° Nobel Biocare zygomatic implants)</i>	45° and 60° <i>(used with compatible 0° Nobel Biocare zygomatic implants)</i>	straight/no angulation, 17° and 30° angulated	Same as Reference Device #6.
<b>Multi-unit Abutment and Screw Material</b>	MUAs and Screw: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) (ASTM F136)	MUA and Screw: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) (ASTM F136)	MUA and Screw: Titanium alloy Ti-6Al-4V (90% titanium, 6% aluminum, 4% vanadium) (ASTM F136)	Same as Reference Device #6.
<b>Multi-unit Abutment and Screw Surface Treatment</b>	MUA: anodization (Xeal)  Screw: partial DLC coated (screw body)	MUA: none  Screw: partial DLC coated (screw body)	MUA: anodization (Xeal)  Screw: DLC coated	Same as Reference Device #8.
<b>Multi-unit Abutment Surface Topography</b>	Xeal – Single level surface: Sa (area roughness) <0.8 µm	Ra < 3.2 µm	Xeal – Single level surface: Sa <0.8 µm	Same as Reference Device #8.

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma CC (45° and 60°) Screw: 45°/60° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws	<b>Reference Device #6</b> Multi-unit Abutment Ext Hex (45° and 60°) Screw: NobelZygoma 0° Angled Multi-Unit Abutment Screw	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal Conical Connection	<b>Comparison</b>
<b>Multi-unit Abutment Hydrophilic surface treatment</b>	Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt on whole abutment surface. Salt concentration: 0.01 – 2.35µg/mm <sup>2</sup>	None	Soluble salt (protective) layer: Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt on whole abutment surface. Salt concentration: 0.01– 2.35 µg/mm <sup>2</sup>	Same soluble salt (protective layer) as Reference Device #8.
<b>Packaging, Sterility and Shelf-life - Multi-unit Abutments</b>				
<b>Multi-unit Abutment Packaging</b>	Polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lid forming a single sterile barrier system.  <i>co-packed with screws and abutment holder</i>	Polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lid forming a single sterile barrier system.  <i>co-packed with screw</i>	Polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lid forming a single sterile barrier system.  <i>co-packed with screw and abutment holder</i>	Same as Reference Device #6.
<b>Multi-unit Abutment Sterile at supply</b>	Yes (Gamma sterilization SAL 10 <sup>-6</sup> )	Yes (Gamma sterilization SAL 10 <sup>-6</sup> )	Yes (Gamma sterilization SAL 10 <sup>-6</sup> )	Same as Reference Device #6.
<b>Multi-unit Abutment Shelf life</b>	5 years	5 years	5 years	Same as Reference Device #6.
<b>Multi-unit Abutment Initial processing needed</b>	No	No	No	Same as Reference Device #6.
<b>Packaging, Sterility and Shelf-life – Screws (standalone)</b>				
<b>Screw Packaging</b>	Polyethylene terephthalate glycol (PETG) blister sealed with a Tyvek lid forming a single sterile barrier system	Polyethylene terephthalate glycol (PETG) blister with a Tyvek lid	N/A	Same packaging materials as Reference Device #6.
<b>Screw -Sterile at supply</b>	Yes (Gamma sterilization SAL 10 <sup>-6</sup> )	No <i>(see packaging, sterility, and shelf-life for MUAs)</i>	N/A	Same as Multi-Unit Abutment Reference Device #6.
<b>Screw Shelf life</b>	5 years	N/A <i>(see packaging, sterility, and shelf-life for MUAs)</i>	N/A	Same as Multi-Unit Abutment Reference Device #6.

	<b>Subject Devices</b> Multi-unit Abutment Xeal Zygoma CC (45° and 60°) Screw: 45°/60° NobelZygoma Multi-unit Abutment Xeal Zygoma Screws	<b>Reference Device #6</b> Multi-unit Abutment Ext Hex (45° and 60°) Screw: NobelZygoma 0° Angled Multi-Unit Abutment Screw	<b>Reference Device #8</b> Multi-unit Abutment (MUA) Xeal Conical Connection	<b>Comparison</b>
<b>Screw Initial processing needed</b>	No	Yes <i>(see packaging, sterility, and shelf-life for MUAs)</i>	N/A	Subject Devices are single-use and provided sterile. No reprocessing submitted as part of this 510(k).
<b>Anatomical location and Use - Multi-unit Abutments and Screws</b>				
<b>Reusability</b>	Single-use	Single-use	Single-use	Same as Reference Device #6.
<b>Duration of use</b>	Permanent implantable	Permanent implantable	Permanent implantable	Same as Reference Device #6.
<b>Anatomical location</b>	Oral cavity - upper jaw	Oral cavity - upper jaw	Oral cavity – upper or lower jaw	Same as Reference Device #6.

## 1.7.5 Similarities between the Subject and the Predicate Device(s)

### Subject NobelZygoma TiUltra Implants

The similarities between the Subject Device line NobelZygoma TiUltra Implants and the respective Predicate Devices (Primary Predicate, Reference Device #1, Reference Device #2, Reference Device #3 and Reference device #7) are as follows:

- The Intended Use of the Subject NobelZygoma TiUltra implants is identical to the Primary Predicate Device and Reference Device #1.
- The Indications for Use of the Subject NobelZygoma TiUltra implants are the same to the Primary Predicate Device (NobelZygoma 45° Implants), Reference Device #1 (NobelZygoma 0° Implants), Reference Device #2 (Zaga Zygomatic System) and Reference Device #3 (Noris Medical Zygomatic Implants) but conveyed with differences in choice of words.
- The Subject Implants, similar to the Reference Device #3 are intended for extra-maxillary placement.
- The Subject and Predicate Devices feature largely identical fundamental design. All Devices are parallel-walled implants with a threaded apex to anchor to the zygomatic bone.
- The Subject NobelZygoma TiUltra implants, similar to the Primary Predicate, the Reference Device #1 and the Reference Device #3 have an unthreaded shaft and collar and are available in 0° and/or 45° angulations. The Reference #2 features a 55° angulation at the head of the implant.
- The Subject Device, Primary Predicate and Reference Device #1 shared the same thread design, implant tip design and are made of unalloyed titanium grade 4 (per ASTM F67). The surface treatment is anodic oxidation for all these implants. The Reference Device #2 and the Reference Device #3 are also titanium-based implants (unalloyed titanium grade 4 and titanium alloy Ti6Al4V).
- The profiles of the Subject Implants are aligned across their entire length up to their respective connection interfaces and have a unified diameter (3.9mm shaft/apex and 4.3mm implant neck). The Subject Implants diameter is almost the same to the Primary Predicate diameter (3.95mm shaft, 3.9mm apex and 4.3mm implant neck). The Reference Device #2 presents a similar implant diameter with 4.3mm at the coronal region for the ZAGA round (or 4.3mm with 3.35 mm flat for the ZAGA flat) and 3.4 mm at the apical region. The Reference Device #3 also has a similar implant diameter (4.2mm neck and 3.5mm apex).

- At the collar region all Nobel Biocare implants incorporate a regular platform width (RP). The Subject NobelZygoma 45°Ext Hex TiUltra Implant presents the same Ext Hex connection as the Primary Predicate, while the Subject NobelZygoma 0°CC TiUltra Implant features a Connical Connection similar to the Reference Device #7.
- The Subject Devices are pre-assembled and co-packed with an implant mount and implant mount screw similar to the Primary Predicate.
- The Subject and all Predicate Devices are single-use implants, provided sterile (gamma sterilization). All Nobel Biocare implants share the same Sterility Assurance Level (SAL  $10^{-6}$ ), have a shelf-life of 5 years, and are sterilized in the same contract sterilizer(s).

### **Subject Multi-unit Abutment Xeal Zygoma**

The similarities between the Subject Device line Multi-unit Abutments Xeal Zygoma and the respective predicate and reference devices (Reference Devices #4, #5, #6 and #8) are as follows:

- The Subject Multi-Unit Abutments Xeal Zygoma have the same Intended Use and Indications as the predicate Multi-Unit Abutments (Reference Device #4, #5 and #6).
- The fundamental technology and essential geometry of the Subject Multi-unit Abutment Xeal Zygoma External Hex is largely the same as for the existing predicate and reference devices. The Subject Devices have the same angulation (straight and 17°, 45° and 60°), width, platform compatibility (RP) as the respective Reference Device (#4, #5 and #6).
- The Subject Devices are made from Titanium alloy (Ti-6Al-4V) same as the Reference Devices #5 and #6.
- All devices are provided sterile (gamma irradiation, SAL  $10^{-6}$ ) and are single-use.

#### **In addition, for Multi-unit Abutment Xeal Zygoma External Hex (Straight and 17°)**

- Similarly to the Predicate Devices, the Subject Devices are co-packed with a multi-unit abutment screw and an abutment holder. The abutment holders do not remain in the patient and are made from the same materials as the respective abutment holder predicate and reference devices.
- The Subject straight and 17° MUAs, same as the predicate/reference devices, feature an external hexagonal connection and are used with compatible Nobel Biocare 45° zygomatic implants.

#### **In addition, for Multi-unit Abutment Xeal Zygoma CC (45° and 60°)**

- The Subject 45° and 60° MUAs, same as the predicate/reference devices, are used with compatible Nobel Biocare 0° zygomatic implants.

### **Subject NobelZygoma Multi-unit Abutment Xeal Zygoma Screws**

The similarities between the Subject Device line NobelZygoma Multi-unit Abutment Xeal Zygoma Screws and the respective predicate and reference devices (Reference Devices #4, #5 and #6) are as follows:

- The Intended Use and Indications for use of the Subject Screws are the same as the respective Reference Devices (#4, #5 and #6).
- Like the Predicate/Reference Screws, the Subject Screws are pre-manufactured dental implant screws designed to fasten dental implant system components to a dental implant or to another component. The screw thread engages the internal thread of implant while the screw head engages the seat feature on abutment. Tightening of the screw applies compressive force between the implant and abutment.
- All Subject and Predicate/Reference Screws are made from titanium alloy (Ti-6Al-4V) and are partially DLC (Diamond Like Carbon) coated. The Subject Screws feature the same screwdriver interphase as the respective Predicate/Reference Device.
- The Subject straight Screws are available in four sizes to fit the varied straight Multi-Unit Abutment heights, plus two single-sized screws for the 45°/60° Multi-Unit Abutments and the 17° Multi-Unit Abutments. The Subject Screw length for the 17° MUAs is the same as the respective Reference Device #5.
- All Subject and Predicate/Reference Screws are single-use and available co-packed with the respective Multi-unit Abutments. When co-packed with the respective MUAs, all screws are sterile (gamma irradiation, SAL 10<sup>-6</sup>) and in the same packaging system with a shelf-life of 5 year. The Subject Screws are also available individually packed (sterile version). Reference Devices #5 and #6 are also available individually packed (non-sterile).

## **1.7.6 Differences Between the Subject and Predicate Device(s)**

### **Subject NobelZygoma TiUltra Implants**

There are no significant differences between the Subject Device line NobelZygoma TiUltra Implants and the respective Predicate/Reference Devices but there are minor differences as follows:

- A different choice of words on the instructions for immediate loading included in the Indications for Use of the Subject NobelZygoma 45°Ext Hex TiUltra is provided when compared to the Primary Predicate (NobelZygoma 45° Implants). The indications for use of the Subject Devices includes the zygomatic bone for consistency with the anatomical placement of the device.

- The Subject Implants and Reference Device #3 are intended for extra-maxillary applications, whereas the Primary Predicate and Reference Devices #1 and #2 are intended for a broader range of clinical applications, including intra-sinus applications.
- While the overall macro-design of the Subject Devices and the respective predicate and reference devices is the same,
  - the diameter of the Subject NobelZygoma 0° TiUltra is unified with the 45° angulated zygomatic implants and is smaller when compared to the diameter of the Reference Device #1 (NobelZygoma 0° Implants).
  - the Subject NobelZygoma 0° TiUltra Implant feature a conical connection similar to the Reference Device #3 and the Reference Device #7.
  - the Subject NobelZygoma 45° Implants introduces a modified implant mount design with an overall slimmer design and a more compact connection interface when compared to the Primary Predicate. In addition, The Subject NobelZygoma 0° CC TiUltra is also provided assembled with a new compatible implant mount and screw.
  - The Subject Devices are available in implant lengths of up to 60 mm, similar to Reference Device #2.

These modifications do not raise different questions of safety and effectiveness. The implant length range of the Subject Devices (from 30mm to 60mm) is the same as that of the Reference Device #2. The additional lengths and modified features were tested whenever deemed to represent a worst-case. Worst-case fatigue testing was conducted to demonstrate that the Subject Device performs at least as well as the defined benchmark reference system and that the difference does not raise different questions of safety and effectiveness.

- The Subject Implants introduce a modified surface topography (TiUltra) with a soluble salt (protective) layer as surface preservation. This TiUltra surface technology, consisting of a multi-level surface topography and including a soluble salt (protective) layer, is already applied to existing Nobel Biocare TiUltra dental implants (e.g., Reference Device #7).
  - Comparison with Reference Device #7:

The Subject Devices have a two-level surface topography, compared to the three-level topography of Reference Device #7 (different intended use and indications). The surface roughness of the two-level design falls within the roughness range of the three-level surface. The soluble salt (protective) layer in the Subject Devices is identical in composition and concentration to that of Reference Device #7.
  - Comparison with Reference Device #3:

Both zygomatic implants are unthreaded at the shaft/collar area (Level 1). The Subject Devices exhibit a rougher surface at Level 1, as demonstrated by comparative verification testing.

- Surface Treatment Comparison:

The Subject Devices, along with the Primary Predicate, Reference Device #1 and Reference Device #7 are anodized. In contrast, Reference Device #3 features a machined surface at the coronal/shaft region and a resorbable blast media surface treatment at the distal region.

The TiUltra surface of the Subject Devices does not raise new questions regarding substantial equivalence. This is supported by comparative roughness verification testing with Reference Device #3. Real-world evidence (RWE) on the Subject Devices, along with clinical data comparing NobelReplace CC PMC (machined collar) and NobelReplace CC TiUnite (anodized collar), as well as clinical data on the Nobel Biocare TiUltra implant family, support the surface treatment of the Subject Devices at Level 1. This is further supported by worst-case fatigue testing, biocompatibility evaluation, and sterility and packaging performance.

- The Subject Devices present a single-sterile barrier packaging configuration similar to Nobel Biocare N1 TiUltra Implants (K211109).

### **Multi-unit Abutments Xeal Zygoma**

There are no significant differences between the Subject Device line Multi-unit Abutments Xeal Zygoma and the respective Predicate/Reference Devices but there are minor differences as follows:

- The Subject Devices have a slightly different profile and come in different height variants with new sizes being introduced when compared to the Reference Devices #4, #5 and #6 and include heights of ca.:
  - Straight, 45° and 60° MUAs: 3mm, 5mm, 7mm, and 9mm
  - 17° MUAs: 3mm and 5mm

Worst-case fatigue testing was conducted to demonstrate that the Subject system performs at least as well as the benchmark reference system and that the differences do not raise different questions of safety and effectiveness.

- The Subject Devices are provided with surface anodization (Xeal), with a surface roughness (Sa) of <0.8µm, and covered by a soluble (protective) layer, whereas the the Reference Devices #4, #5 and #6 are machined (profile roughness (Ra) of <3.2µm). The surface topography and salt surface preservation layer (salt chemical

composition and salt concentration) of the Subject Devices is the same as the Reference Device #8. Biocompatibility evaluation and fatigue testing demonstrated that this technological difference does not raise different questions of safety and effectiveness.

#### In addition, for 45° and 60° Multi-unit Abutments Xeal Zygoma Ext Hex

- The Subject 45° and 60° Multi-unit Abutments (MUAs) incorporate a retention thread feature to enable pre-assembly of the Abutment screw prior to MUA placement and to help prevent loss of screw during MUA placement and removal.
- The Subject Multi-unit Abutments (MUAs) incorporate the MUA plus interface design, to enable the connection of the Temporary Snap Copings. This functionality, already integrated in Reference Device #8, is provided to simplify the workflow during the try-in and adjustment of the provisional prosthesis.
- The Subject 45° and 60° Multi-unit Abutment feature a conical connection similar to the Reference Device #8. Worst-case fatigue testing demonstrated that this technological difference does not raise different questions of safety and effectiveness and that the Subject Devices perform at least as good as the benchmark reference system.
- The Subject 45° and 60° Multi-unit Abutments are co-packed with an abutment holder while the Reference Device #6 is not. The abutment holders, which do not remain in the patient, are made from Titanium alloy, same as the Reference Device #5.

#### NobelZygoma Multi-unit Abutment Xeal Zygoma Screws

There are no significant differences between the Subject Device line NobelZygoma Multi-unit Abutment Xeal Zygoma Screws and the respective Predicate/Reference Device but there are minor differences as follows:

- The range of the Subject straight Screws is broader than the range of the respective Predicate/Reference Screws (Reference Device #4) to accommodate the varied Subject straight Multi-Unit Abutment heights.
- The 45°/60° MUA screw length seat position is higher in the Multi-unit Abutment to minimise the volume of free space.
- The Subject Screw length for the 45°/60° MUAs is within range of the length of the Reference Device #6.
- The Subject Screws when provided individually packed are provided sterile in the same sterile packaging system as when provided co-packed with the Subject compatible MUAs. Predicate/Reference Screws (Reference #5 and #6) when

provided individually packed are provided non-sterile and require reprocessing prior to use. The Subject Devices and provided sterile, are single-use and are not intended to be reprocessed by the end user.

### **Overall Conclusion:**

Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, the Subject NobelZygoma TiUltra Implant system is deemed to be substantially equivalent to the Predicate Devices. The technological differences do not raise new concerns of substantial equivalence.

The Subject NobelZygoma TiUltra Implant system does not introduce a fundamentally new scientific technology, and nonclinical performance testing and clinical performance data demonstrates that the Subject system is substantially equivalent. The performance testing and clinical performance data described in this submission supports the conclusion that the Subject Devices perform as well as the Predicate Devices for its intended use.

## **1.8 Non-Clinical and/or Clinical Tests Summary & Conclusions:**

### **Summary of Non-Clinical Testing**

Non-clinical testing was performed on the Subject Device lines NobelZygoma TiUltra Implants, Multi-unit Abutments Xeal Zygoma and NobelZygoma Multi-unit Abutment Xeal Zygoma Screws:

- The fatigue performance of the NobelZygoma TiUltra Implant system was evaluated in a dynamic loading test method based on ISO 14801 adapted for zygomatic implants and according to FDA Guidance Document entitled, “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” (May 12, 2004).
- Implant insertion torque testing was performed following the respective implant site preparation protocols in a surrogate bone material to demonstrate that the site preparation protocol allows to seat the implants applying equal or less torque than for the benchmark reference system.
- Magnetic Resonance testing for the Subject NobelZygoma TiUltra Implant system has been performed in accordance with ASTM F2052-21, ASTM F2213-17, ASTM F2182-19e2, ASTM F2119-24 and FDA Guidance GUI01500059 “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”, issued

October 10, 2023. The Subject NobelZygoma TiUltra Implant system can be labeled as MR Conditional according to ASTM F2503.

- Verification of biocompatibility of the final devices in accordance with ISO 10993-1 series and FDA Guidance Document entitled, Use of international standard ISO 10993-1 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” (Sept. 8, 2023).
- The packaging performance was validated to ensure the packaging performs as intended in accordance with ISO 11607-1, ISO 11607-2, ASTM D4169, ASTM D4332, ASTM F1886 and ASTM F2096. Shelf-life was confirmed in accordance with ASTM F1980. The packaging validation has passed all predefined validation activities. It has been proven that the final packed product after simulated transportation and distribution testing maintains packaging integrity.
- Sterilization validation was conducted in accordance with ISO 11137-1, ISO 11137-2, ISO 11137-3, AAMI TIR29 and AAMIT TIR 35.
- Endotoxin pyrogenicity testing was performed to demonstrate that the endotoxin limit through LAL test according to the United States Pharmacopeial Convention was respected. Periodic endotoxin monitoring is conducted in accordance with AAMI ST72.
- Surface modification testing of the implant body was performed to support the equivalency of the modified surface topography. Comparative roughness verification using white light interferometry (WLI) confirmed that the Subject Devices exhibit a rougher surface at collar/shaft compared to the Reference Device #3.

### Summary of Clinical Performance Data

Multiple sources of real-world evidence were provided to demonstrate the performance of the Subject Device.

The body of clinical data included supportive published literature along with real-world evidence in form of post-market surveillance data and clinical case studies.

### Published Literature:

- Three clinical studies involving 176 similar zygomatic implants in non-full arch applications, including NobelZygoma TiUnite, Noris Medical Zygomatic and JDZygoma dental implants, were provided to support the use of the Subject Devices in non-full arch applications. Reported adverse events include implant failure, soft tissue recession, and local inflammation. One patient (out of 167) died of myocardial infarction during the COVID-19 pandemic.
- Comparative clinical data to demonstrate substantially equivalence outcomes of similar zygomatic implant devices used in a quad versus a hybrid zygoma approach

was provided. The main body of clinical data included a systematic literature review and two clinical studies involving Nobel Biocare zygomatic implants (Zygoma RP, Brånemark System Zygoma TiUnite and NobelZygoma TiUnite implants).

- The systematic review reported a mean implant survival rate of 97.4% for the quad configuration. For quad zygoma approach, patients reported postoperative discomfort, paresthesia, and hematomas, all of which healed within a few days to weeks. Some peri-implant inflammation and bleeding were observed but did not affect osseointegration. Additional studies documented instances of unilateral sinusitis, hypoesthesia, soft tissue inflammation, and implant failure, with appropriate treatments leading to resolution. There were also occurrences of orbital cavity penetration, infection, sinusitis, abutment screw fracture, and prosthesis fracture, all of which were addressed with suitable interventions.
- The two clinical studies involving a total of 317 patients treated with zygomatic implants using quad, hybrid, or mixed approaches reported implant survival rates of 100% ( $n = 15$ , minimum follow-up of 79 months, quad/hybrid) and 89.9% ( $n = 302$ , mean follow-up of 7.9 years, quad/hybrid/mix). No implant-related adverse events were reported in the first study, while sinusitis was the most commonly observed complication in the second. The second study concluded that the quad approach was not associated with a statistically significant increase in implant loss compared to the classic scheme ( $p = 0.109$ ).

In addition, a total of 40 clinical publications were provided to support the established history of safe clinical use of zygomatic implants in a quad configuration. These studies primarily involved various models of Nobel Biocare zygomatic implants (Zygoma RP, Brånemark System Zygoma TiUnite, NobelZygoma TiUnite), as well as other zygomatic systems such as Noris, Straumann and Southern implants, and utilized various surgical techniques including extra-maxillary. None of the studies reported a survival rate below 90%.

Real-world evidence on the Subject Devices and clinical data on NobelReplace and the TiUltra implant family was presented to address any potential additional difference in technological characteristics, such as surface treatment and topography, of the Subject Implants.

- Post-market surveillance data was collected for the Subject Devices from July 2024 till May 2025. Complaint rates of the Subject Devices were compared to the complaint rates of the NobelZygoma TiUnite implants (Primary Predicate Device and Reference Device #1) and found to have similar performance in terms of osseointegration.

- Seven clinical cases with a total of 16 NobelZygoma TiUltra implants in maxillary rehabilitation, including hybrid and quad configuration, were presented. No intraoperative or postoperative complications were reported.
- 36 clinical publications including clinical data on NobelReplace CC PMC (machined collar), NobelReplace CC TiUnite (anodized collar), and Nobel Biocare TiUltra implant family were provided to support the surface treatment/roughness of the Subject Devices at the implant body (collar/shaft).
  - Both Nobel Replace CC Implant lines (machined vs anodized collar) show comparable safety profiles with respect to osseointegration and similar mean survival rates.
  - The clinical data on TiUltra Implants reported a mean implant survival rate of 99.5. Except for one study that reported mild inflammation, plaque, or bleeding, no adverse events were reported.

In addition, post-market surveillance data on the TiUltra Implants show osseointegration complaint rates comparable to those of the respective TiUnite implant family.

Overall, based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the Subject NobelZygoma TiUltra Implant system is deemed to be substantially equivalent to the Predicate Devices. The technological differences do not raise new questions of safety and effectiveness.