February 18, 2026

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

Re: K252197
Trade/Device Name: Nobel Biocare S Series Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: July 14, 2025
Received: January 21, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

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

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252197

Device Name
Nobel Biocare S Series Implants

Indications for Use *(Describe)*

NobelActive® S TiUltra™, NobelActive® S TiUnite®

NobelActive® S TiUltra™ and NobelActive® S TiUnite® 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® S TiUltra™ and NobelActive® S TiUnite® 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.

NobelReplace® S TiUltra™, NobelReplace® S TiUnite®

NobelReplace® S TiUltra™ and NobelReplace® S TiUnite® 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® S TiUltra™ and NobelReplace® S TiUnite® implants are indicated for single or multiple unit restorations.

The NobelReplace® S TiUltra™ and NobelReplace® S TiUnite® implants can be used in splinted or non-splinted applications.

The NobelReplace® S TiUltra™ and NobelReplace® S TiUnite® implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

NobelParallel™ S TiUltra™, NobelParallel™ S TiUnite®

NobelParallel™ S TiUltra™ and NobelParallel™ S TiUnite® 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™ S TiUltra™ and NobelParallel™ S TiUnite® implants are indicated for single or multiple restorations in splinted or non-splinted applications.

This can be achieved by 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.

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 Vastra Hamngatan 1 Goteborg 411 17 Sweden
Submitted By:	Nobel Biocare Services AG Balz-Zimmerman-Strasse 7 8302 Kloten Switzerland
Contact Person:	Bernice Jim, PhD
E-Mail:	regulatory.affairs.nb@envistaco.com
Telephone:	+41 43 211 42 00
Prepared By:	Heather Yates
Date Prepared	February 13, 2026

1.2 Device Name

Proprietary Name:	Nobel Biocare S Series Implants
Common Name:	Dental Implant
Classification Name:	Endosseous Dental Implant
Regulation Number:	21 CFR 872.3640
Device Class:	Class II
Product Code:	DZE

1.3 Predicate and Reference Devices

Primary Predicate device

K202344, TiUltra Implants and Xeal Abutments

Reference Devices:

1	K230108	Straumann BLC and TLC Implants
2	K142260	NobelActive
3	K173418	NobelParallel Conical Connection
4	K073142	NobelReplace Hexagonal Implant
5	K212125	Nobel Biocare Dental Implant Systems Portfolio - MR Conditional

6	K023113	Replace TiUnite Endosseous Implant
7	K071370	NOBELACTIVE INTERNAL CONNECTION IMPLANT
8	K083100	GOLDADAPT NON-ENGAGING NOBELACTIVE NP & RP, GOLDADAPT ENGAGING NOBELACTIVE NP & RP
9	K132746	NOBELPROCERA ANGULATED SCREW CHANNEL ABUTMENT CONICAL CONNECTION
10	K233208	NobelProcera Titanium ASC Abutment, Omnigrip Clinical Screw Titanium
11	K200040	Universal Base Conical Connection (CC)
12	K132749	NOBELPROCERA OVERDENTURE BAR
13	K161416	Multi-unit Abutment Plus
14	K202452	NobelProcera Zirconia Implant Bridge
15	K240346	NobelProcera Zirconia Implant Bridge
16	K041236	PROCERA IMPLANT BRIDGE, MODELS 15-1001, 15-1002, 15-1051, 15-1052
17	K133731	NOBELACTIVE WIDE PLATFORM (WP)
18	K061003	SFB & CFB IMPLANTS
19	K161435	Temporary Snap Abutment
20	K091756	NobelProcera Ti Abutment
21	K062566	NOBELREPLACE TAPERED CONICAL CONNECTION
22	K072570	NOBELACTIVE MULTI UNIT ABUTMENT
23	K160158	NobelProcera HT ML FCZ Implant Bridge and Framework

1.4 Device Description Summary

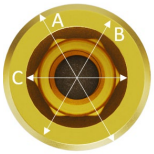
The Subject Device, Nobel Biocare S Series Implants, comprises of six Device Lines NobelActive S TiUltra™, NobelParallel™ S TiUltra™, NobelReplace S TiUltra™, NobelActive S TiUnite, NobelParallel™ S TiUnite, NobelReplace S TiUnite

Nobel Biocare S Series Implants are intended for use as an endosseous dental implant in the maxilla or mandible for anchoring or supporting dental prostheses to restore chewing function.The Subject Device features a consistent diameter at the implant-abutment interface, regardless of the implant size or type. This means that the prosthetic components, such as abutments and restorative elements, have uniform dimensions and connections across all implant sizes within the system. The connection used is the Narrow Platform (NP) conical connection.

The implant bodies of the Subject Devices and Predicate devices are the same. This allows use of the same drills and drilling protocols, rescue procedures and rescue tools. By using the existing Narrow Platform connection, the same prosthetic workflows, prosthetic components, and lab components can be used.

The implants are available in different sizes as listed in Table 1.

Table 1. **Implant specifications**

Implant line	Conical connection size				Lengths [mm]
		A - Implant diameter [mm]	B - Platform diameter [mm]	C - Abutment interface [mm]	
NobelActive® S TiUltra™/TiUnite®	NP	3.5	3.5	3.0	8.5, 10, 11.5, 13, 15, 18
	NP	4.3	3.9	3.0	8.5, 10, 11.5, 13, 15, 18
	NP	5.0	3.9	3.0	8.5, 10, 11.5, 13, 15, 18
	NP	5.5	3.9	3.0	7, 8.5, 10, 11.5, 13, 15
NobelParallel™ S TiUltra™/TiUnite®	NP	3.75	3.5	3.0	7, 8.5, 10, 11.5, 13, 15, 18
	NP	4.3	3.9	3.0	7, 8.5, 10, 11.5, 13, 15, 18
	NP	5.0	3.9	3.0	7, 8.5, 10, 11.5, 13, 15, 18
	NP	5.5	3.9	3.0	7, 8.5, 10, 11.5, 13, 15
NobelReplace® S TiUltra™/TiUnite®	NP	3.5	3.5	3.0	8, 10, 11.5, 13, 16
	NP	4.3	3.9	3.0	8, 10, 11.5, 13, 16
	NP	5.0	3.9	3.0	8, 10, 11.5, 13, 16

The Nobel Biocare S Series Implants are manufactured from commercially pure titanium and incorporate a conical connection (Size Narrow Platform (NP)) with a hex interface in the collar region, which combines with Nobel Biocare's existing prosthetic Abutment portfolio cleared in K071370, K083100, K132746, K233208, K202344, K200040, K132749, K161416, K202452, K240346, K041236, K133731, K061003 and K161435.

Table 2 outlines which single-unit restoration abutments with an NP connection can be used with the subject device.

Table 2. Compatible Single-unit Restoration Abutments for NobelBiocare S Series Implants

Single-Unit Restoration Abutments (Proprietary Name)
Group 1 – Titanium Abutments
Esthetic Abutment Conical Connection (with NP Connection only) (K071370)
Snappy Abutments (with NP Connection only) (K071370)
Universal Base Conical Connection(with NP connection only) (K200040)
NobelProcera Abutments Conical Connection Titanium (with NP Connection only) (K071370)
NobelProcera Abutments Conical Connection Titanium (with NP connection only) (K233208)
Group 2 – Gold Abutments
GoldAdapt Conical Connection (with NP connection only) (K083100)
Group 3 – Titanium and Zirconia Abutments
NobelProcera Angulated Screw Channel Abutment (with NP connection only) (K132746)
NobelProcera FCZ Implant Crown (with NP connection only) (K132746)

Table 3 outlines which multi-unit restoration abutments and bridges with an NP connection can be used with the subject devices.

Table 3. Compatible Multi-unit Restoration Abutments for Nobel Biocare S Series Implants

Multi-unit Restoration Abutments and Bridges (Proprietary Name)
Procera Implant Bridge Titanium (K041236)
Multi-Unit Abutment Plus Conical Connection (with NP connection only) (K161416)
Multi-Unit Abutment Xeal Conical Connection (wit NP connection only) (K202344)
NPr Impl Bar Overdenture Ti (K132749)
NobelProcera Implant Bridge Zirconia (K202452; K240346)

Table 4 outlines the temporary and healing restorations with an NP connection that can be used with the subject devices. ¨

Table 4. Compatible Temporary and Healing Restoration Abutments for Nobel Biocare S Series Implants

Temporary and Healing Restorations (Proprietary Name)
Healing Abutment Conical Connection (with NP connection only) (K133731)
Temporary Snap Abutment (with NP connection only) (K161435)
Temporary Abutment Conical Connection (with NP connection only) (K061003)

Table 5 lists the corresponding submissions where compatible Class II accessories with an NP connection were previously identified.

Table 5. List of 510(k) Class II Compatible Accessories to Nobel Biocare S Series Implants

Compatible Accessories
NobelReplace Tapered Conical Connection, Cover Screw Conical Connection NP (K062566)
NobelActive Internal Connection Implant, Clinical Screw Conical Connection NP (K071370
NobelActive Multi Unit Abutment, Screw Multi-Unit Angled Abutment Conical Connection NP (K072570)
NobelProcera HT ML FCZ Implant Bridge and Framework, Metal Adapter (NP Only) (K160158)
NobelProcera® Titanium ASC Abutment, Omnigrip Clinical Screw Titanium CC NP (K233208)
NobelProcera Angulated Screw Channel Abutment Conical Connection, Omnigrip™ Clinical Screw CC NP (K132746)

The On1™ Base/On1™ Base Xeal must not be used in combination with NobelActive® S, NobelParallel™ S, NobelReplace® S implants.

NobelActive® S, NobelParallel™ S, NobelReplace® S implants in combination with NobelProcera® Angulated Screw Channel Abutment and NobelProcera® FCZ Implant Crown are indicated for maxillary lateral and mandibular central/lateral incisors only.

NobelActive® S, NobelParallel™ S, NobelReplace® S implants may be used in combination with NobelProcera® Angulated Screw Channel Abutment and NobelProcera® FCZ Implant Crown up to a maximum angulation of 20°

NobelActive® S, NobelParallel™ S, NobelReplace® S implants may be used in combination with GoldAdapt Engaging CC NP abutments in straight (0°) configurations only.

No angulation is allowed for Universal Base Conical Connection Abutments when mated with the NobelActive® S, NobelParallel™ S, NobelReplace® S implants with diameters greater than 3.5mm.

1.5 Indications for Use

NobelActive® S TiUltra™, NobelActive® S TiUnite®
NobelActive® S TiUltra™ and NobelActive® S TiUnite® 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® S TiUltra™ and NobelActive® S TiUnite® 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.

NobelReplace® S TiUltra™, NobelReplace® S TiUnite®
NobelReplace® S TiUltra™ and NobelReplace® S TiUnite® 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® S TiUltra™ and NobelReplace® S TiUnite® implants are indicated for single or multiple unit restorations.

The NobelReplace® S TiUltra™ and NobelReplace® S TiUnite® implants can be used in splinted or non-splinted applications.

The NobelReplace® S TiUltra™ and NobelReplace® S TiUnite® implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

NobelParallel™ S TiUltra™, NobelParallel™ S TiUnite®
NobelParallel™ S TiUltra™ and NobelParallel™ S TiUnite® 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™ S TiUltra™ and NobelParallel™ S TiUnite® implants are indicated for single or multiple restorations in splinted or non-splinted applications.

This can be achieved by 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.

1.6 Technological Comparison

The Nobel Biocare S Series Implants consists of six device lines; NobelActive S TiUltra™, NobelParallel™ S TiUltra™, NobelReplace S TiUltra™, NobelActive S TiUnite, NobelParallel™ S TiUnite, NobelReplace S TiUnite.

The subject device and the predicate device have the same Indications for Use, Macro design and material surface treatment. They are single-use implants, delivered in the same packaging configuration, provided sterile (gamma sterilization, SAL 10-6) with a shelf-life of 5 years. Both the subject devices and predicate device are labelled as MR Conditional

The design concept of Subject Device Lines combines the existing outer geometry of the implant bodies of the predicate devices but have the same Narrow Platform (NP) conical connection for all implant diameters. This introduces an increased platform shift. This contrasts with the Predicate which have a larger size conical connection (Regular Platform (RP) or Wide Platform (WP)) on implants with diameters larger than 3.75mm. Only Predicate Devices with diameters of 3.75mm or 3.5mm feature the Narrow Platform (NP) connection. The use of the existing NP Platform allows the use of existing prosthetic workflows, rescue procedures, prosthetic components, lab components, and rescue tools.

The differences between the subject device and the predicate do not raise different questions of substantial equivalence. Additional implant diameter to connection size combinations 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.

1.6.1 Substantial Equivalence Table:

Technological Characteristics	Subject Device - Nobel Biocare S Series Implants	Primary Predicate Device TiUltra implants - K202344	Reference Device #1 Straumann BLC and TLC Implants - K230108	Reference Device #2 NobelActive - K142260	Comparison
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	Same as Predicate
Product Code	DZE	DZE	DZE, NHA	NHA, DZE	Same as Predicate
Indications for Use	**NobelActive® S TiUltra™, NobelActive® S TiUnite®** NobelActive® S TiUltra™ and NobelActive® S TiUnite® 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® S TiUltra™ and NobelActive® S TiUnite® 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	**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	Straumann dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	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.	Same as Predicate[1]

[1] Note that the Subject Devices do not include 3.0 sizes. Therefore indications pertaining to these devices do not feature in the Subject Devices Indications for Use

Technological Characteristics	Subject Device - Nobel Biocare S Series Implants	Primary Predicate Device TiUltra implants - K202344	Reference Device #1 Straumann BLC and TLC Implants - K230108	Reference Device #2 NobelActive - K142260	Comparison
	sufficient primary stability and appropriate occlusal loading for the selected technique. **NobelReplace® S TiUltra™, NobelReplace® S TiUnite®** NobelReplace® S TiUltra™ and NobelReplace® S TiUnite® 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® S TiUltra™and NobelReplace® S TiUnite® implants are	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. NobelReplace CC TiUltra™ implants are indicated for single or multiple unit restorations.			

Technological Characteristics	Subject Device - Nobel Biocare S Series Implants	Primary Predicate Device TiUltra implants - K202344	Reference Device #1 Straumann BLC and TLC Implants - K230108	Reference Device #2 NobelActive - K142260	Comparison
	indicated for single or multiple unit restorations. The NobelReplace® S TiUltra™and NobelReplace® S TiUnite® implants can be used in splinted or non-splinted applications. The NobelReplace® S TiUltra™and NobelReplace® S TiUnite® implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied. **NobelParallel™ S TiUltra™, NobelParallel™S TiUnite®** NobelParallel™ S TiUltra™ and NobelParallel™ S TiUnite® 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.	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.			

Technological Characteristics		Subject Device - Nobel Biocare S Series Implants	Primary Predicate Device TiUltra implants - K202344	Reference Device #1 Straumann BLC and TLC Implants - K230108	Reference Device #2 NobelActive - K142260	Comparison
		NobelParallel™ S TiUltra™ and NobelParallel™ S TiUnite® implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by 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.	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			
Design Features	**Implant Length**	NobelActive S implants 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13mm, 15mm, 18mm NobelParallel S implants 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13mm, 15mm, 18mm NobelReplace S implants	NobelActive TiUltra implants 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13mm, 15mm, 18mm NobelParallel CC TiUltra implants 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13mm, 15mm, 18mm NobelReplace CC TiUltra implants	6mm, 8mm, 10mm, 12mm, 14mm, 16mm, 18mm	7.0mm, 8.5mm, 10.0mm, 11.5mm, 13mm, 15mm, 18mm	Same as Predicate

Technological Characteristics		Subject Device - Nobel Biocare S Series Implants	Primary Predicate Device TiUltra implants - K202344	Reference Device #1 Straumann BLC and TLC Implants - K230108	Reference Device #2 NobelActive - K142260	Comparison
		8.0mm, 10.0mm, 11.5mm, 13mm, 16mm	8.0mm, 10.0mm, 11.5mm, 13mm, 16mm			
	Implant Diameter	NobelActive S implants 3.5mm, 4.3mm, 5.0mm, 5.5mm NobelParallel S implants 3.75mm, 4.3mm, 5.0mm, 5.5mm NobelReplace S implants 3.5mm, 4.3mm, 5.0mm	NobelActive TiUltra implants 3.5mm, 4.3mm, 5.0mm, 5.5mm NobelParallel CC TiUltra Implants 3.75mm, 4.3mm, 5.0mm, 5.5mm NobelReplace CC TiUltra Implants 3.5mm, 4.3mm, 5.0mm	Ø 3.3, 3.75, 4.5, 5.5, 6.5 mm	3.5mm, 4.3mm, 5.0mm, 5.5mm	Same as Predicate
	Platform Compatibility	Conical Connection NP	Conical Connection NP, RP, WP	n/a	Conical Connection NP, RP, WP	The Subject Device has the same implant/abutment connection as the NP of the Predicate.
	Platform shift	NobelActive S implants 0.295-1.175mm NobelParallel S implants 0.388-1.275mm NobelReplace S implants 0.295-1.028mm	NobelActive TiUltra implants 0.295-0.45mm NobelParallel CC TiUltra Implants 0.388-0.778mm NobelReplace CC TiUltra Implants 0.295-0.828mm	0.3-1.9mm	0.295-0.45mm	Within the range of Reference Device #1.
	Macro Design	NobelActive S implants Tapered implant with back-tapered coronal design,	NobelActive TiUltra implants Tapered implant with back-tapered coronal design,	n/a	Tapered implant with back-tapered coronal design,	Same as Predicate

Technological Characteristics		Subject Device - Nobel Biocare S Series Implants	Primary Predicate Device TiUltra implants - K202344	Reference Device #1 Straumann BLC and TLC Implants - K230108	Reference Device #2 NobelActive - K142260	Comparison
		reverse-cutting flutes and double lead threads NobelParallel S implants Double lead thread with groove; Tapered apex with bone cutting flutes, slightly tapered body NobelReplace S implants Tapered implant with single lead threads	reverse-cutting flutes and double lead threads NobelParallel CC TiUltra implants Double lead thread with groove; Tapered apex with bone cutting flutes, slightly tapered body NobelReplace CC TiUltra implants Tapered implant with single lead threads		reverse-cutting flutes and double lead threads	
	Material	Commercially pure titanium	Commercially pure titanium	n/a	Commercially pure titanium	Same as Predicate
	Surface Treatment	Anodic oxidation	Anodic oxidation	n/a	Anodic oxidation	Same as Predicate
	Implant/Abutment Connection	Anodic oxidation on collar and inside the connection	Anodic oxidation on collar and inside the connection	n/a	Machined on collar and inside the connection (NP and RP platforms) Anodic oxidation on collar and inside the connection (WP platform)	Same as Predicate for TiUltra and as Reference #2 for TiUnite surface.
	Surface Topography	TiUltra – Three-level surface [area roughness (Sa) thickness (Thk)]: • Level 0 (collar): o Sa = 0.5–1.5 µm o Thk = 0.166 ± 0.008µm • Level 1 (transition):	TiUltra – Three-level surface [area roughness (Sa) thickness (Thk)]: • Level 0 (collar): o Sa = 0.5–1.5 µm o Thk = 0.166 ± 0.008µm • Level 1 (transition):	n/a		Same as Predicate for TiUltra and as Reference #2 for TiUnite

Technological Characteristics		Subject Device - Nobel Biocare S Series Implants	Primary Predicate Device TiUltra implants - K202344	Reference Device #1 Straumann BLC and TLC Implants - K230108	Reference Device #2 NobelActive - K142260	Comparison
		o Sa = 1.4 ± 0.4µm o Thk = 12.0 ± 1.2µm • 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	o Sa = 1.4 ± 0.4µm o Thk = 12.0 ± 1.2µm • 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	
	Color Coding	No color coding on implants. Packaging is color coded	No color coding on implants. Packaging is color coded	n/a	Color Coding only on the product for the 5.5mm diameter implant (blue). Packaging of all products are color coded	Same as Predicate for TiUltra and as Reference #2 for TiUnite
	Surface preservation	TiUltra – Hydrophilic surface Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt TiUnite – n/a	Hydrophilic surface Sodium dihydrogen phosphate dihydrate and magnesium chloride hexahydrate salt	n/a	n/a	Same as Predicate for TiUltra and as Reference #2 for TiUnite
Packaging		Polyethylene terephthalate (PET) vial with high density polyethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister sealed with (Tyvek) lid (2nd sterile barrier) inside a cardboard box (protective packaging).	Polyethylene terephthalate (PET) vial with high density polyethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister (2nd sterile barrier) inside a cardboard box (protective packaging).	n/a	Polyethylene terephthalate (PET) vial with high density polyethylene (HDPE) cap (1st sterile barrier) placed in a polyethylene terephthalate glycol (PETG) blister (2nd sterile barrier) inside a cardboard box (protective packaging).	Same as Predicate
Sterilization (SAL)		Gamma Radiation (SAL 10^{-6})	Gamma Radiation (SAL 10^{-6})	n/a	Gamma Radiation (SAL 10^{-6})	Same as Predicate

Technological Characteristics	Subject Device - Nobel Biocare S Series Implants	Primary Predicate Device TiUltra implants - K202344	Reference Device #1 Straumann BLC and TLC Implants - K230108	Reference Device #2 NobelActive - K142260	Comparison
MR Compatibility	MR Conditional	MR Conditional (as per K212125)	n/a	MR Conditional (as per K212125)	Same as K212125
Biocompatibility Testing	The final product, as shipped is biocompatible according to ISO 10993-1	The final product, as shipped is biocompatible according to ISO 10993-1	n/a	The final product, as shipped is biocompatible according to ISO 10993-1	Same as Predicate
Performance Testing – Bench	Dynamic loading test for endosseous dental implants.	Dynamic loading test for endosseous dental implants, insertion test.	n/a	Dynamic loading test for endosseous dental implants, insertion test.	Same as Predicate
Clinical Testing	None	None	n/a	None	Same as Predicate

1.7 Non-Clinical Tests Summary & Conclusions:

Non-clinical testing was performed on the Subject devices Nobel Biocare S Series Implants:

- Packaging system performance testing per ASTM D4169
- Dynamic loading testing performed according to ISO 14801 was conducted according to ISO 14801 and the FDA Guidance Document entitled, “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” (May 12, 2004)
- Modified surface treatment information 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) referenced from K202344 for TiUltra Surface and K173418 for TiUnite Surface.
- Referenced from K212125, non-clinical analysis and testing to evaluate the metallic Subject Devices in the MR environment was conducted according to ASTM F2052 (magnetically induced displacement force), ASTM F2213 (magnetically induced torque), ASTM F2119 (image artifact), and ASTM F2182 (RF induced heating), and the FDA guidance document Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment (issued May 2021)Referenced from K202344, K142260, K173418, K073142, biological assessments were performed according to ISO 10993-1 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process' and to the FDA Guidance document 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016' for each subject device. The subject devices are equivalent in material and manufacturing processes to the primary predicate and reference devices, therefore, no new issues regarding biocompatibility were raised and no additional biocompatibility testing was required.
- Referenced from K202344, Endotoxin testing was completed in accordance with:
  - USP 42-NF37:2019, Medical Devices—Bacterial Endotoxin and Pyrogen Tests
  - ANSI/AAMI ST72:2011/ (R)2016, Bacterial endotoxins — Test methods, routine monitoring, and alternatives to batch testing.
- Referenced from K202344, packaging performance testing and sterile barrier shelf-life data of 5 years conducted according to ISO 11607-1:2019, 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

Clinical performance data is not required to establish substantial equivalence for the subject devices.

Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the Subject Devices; Nobel Biocare S Series Implants are deemed to be substantially equivalent to the predicate devices.