Infinitum Eta Ltd.
% Valerie Defiesta-Ng,
Executive Director of Regulatory Affairs
Veranex, Inc.
5420 Wade Park Blvd, Suite 204
Raleigh, NC 27607 USA

November 15, 2024

Re: K233081
Trade/Device Name: NUVENTUS NV.C™ Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 22, 2024
Received: October 22, 2024

Dear Valerie Defiesta-Ng:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sherrill Lathrop Blitzer

for Andrew 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233081

Device Name
NUVENTUS NV.C™ Dental Implant System

Indications for Use *(Describe)*
NUVENTUS NV.C™ Dental Implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. NUVENTUS NV.C™ dental implants may be used for immediate, early or delayed implantation following the extraction or loss of natural teeth. The implants can be placed with immediate loading for single-tooth or multiple teeth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. NUVENTUS NV.C™ Dental Implants are compatible for use with the following prosthetic interfaces.

Implant System Prosthetic Compatibility	Platform Size/Designation
Nobel Biocare Internal Conical Connection (CC)	NP CC
	RP CC

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k)
Summary
K233081
NUVENTUS NV.C™ Dental Implant System
Infinitum Eta Ltd.

November 15,
2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	Infinitum Eta Ltd. HaTnufa St 6 Petah Tikva, 4951024, Israel Telephone: +972-54-5559399
Official Contact	Kobi Shakarchi, Chief Executive Officer
Representative/Consultant	Valerie Defiesta-Ng Veranex, Inc. 5420 Wade Park Blvd., Suite 204 Raleigh, NC 27607 USA Email: valerie.defiesta-ng@veranex.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	NUVENTUS NV.C™ Dental Implant System
Common Name	Endosseous dental Implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous Dental Implant
Regulatory Class	Class II
Product Code	DZE
Secondary Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K142260, NobelActive®, Nobel Biocare AB

Reference Devices
K163349, MIS V3 Conical Connection Dental Implant System, MIS Implants Technologies Ltd.;
K181850, Inversa Implants, Southern Implants (Pty) Ltd.;
K071370, NobelActive Internal Connection Implant, Nobel Biocare AB;
K161435, Temporary Snap Abutment, Nobel Biocare AB;
K161416, Multi-unit Abutment Plus, Nobel Biocare AB

INDICATIONS FOR USE STATEMENT

NUVENTUS NV.C™ Dental Implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. NUVENTUS NV.C™ dental implants may be used for immediate, early or delayed implantation following the extraction or loss of natural teeth. The implants can be placed with immediate loading for single-tooth or multiple teeth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. NUVENTUS NV.C™ Dental Implants are compatible for use with the following prosthetic interfaces.

Implant System Prosthetic Compatibility	Platform Size/Designation
Nobel Biocare Internal Conical Connection (CC)	NP CC
	RP CC

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for NUVENTUS NV.C™ Dental Implant System endosseous dental implants and cover screws. The dental implants are intended to interface with Internal Conical Connection (CC) prosthetic components from Nobel Biocare.

A summary of the subject device implant and the associated compatible OEM prosthetic connection is provided in the table *Summary of Subject Device Implant Designs*.

Summary of Subject Device Implant Designs

Subject Device Implant Description	Platform Designation	Length (mm)*					OEM Prosthetic Compatibility (K071370, K161435, K161416)
Implant, NV.C, Platform NP, Ø3.5 mm	NP	8.5	10	11.5	13	15	Nobel Biocare Internal Conical, NP Platform
Implant, NV.C, Platform NP, Ø4.3 mm	NP	8.5	10	11.5	13	15	Nobel Biocare Internal Conical, NP Platform
Implant, NV.C, Platform RP, Ø5.0 mm	RP	8.5	10	11.5	13	15	Nobel Biocare Internal Conical, RP Platform

* Labeled Length – actual length of the implant is 0.5 mm less than the labeled length.

The subject device dental implants have a conical abutment seating surface on the interior of the implants and internal threads so that prosthetic components may be fastened to the implant. The implant lines have two (2) abutment interface connections with internal geometric features to allow for rotational resistance of the mating abutment. All subject device implants are manufactured from Ti-6Al-4V alloy conforming to ASTM F136.

The external surface of all subject device implants is threaded, and the implant body tapers at the apical end, which includes two (2) cutting flutes. At the coronal end, the Ø4.3mm and Ø5.0mm (body diameter) subject device implants have two (2) fluted features on the body of the implant spaced 180° apart. Each fluted feature has horizontal grooves spaced vertically within the flute surface. The number of grooves within each flute ranges from 3 to 5 and the actual number is a function of the implant length. The Ø3.5mm (body diameter) subject device implants do not have fluted features. The endosseous surface of all subject implants is textured by blasting with resorbable media

The subject device implants are compatible with prosthetic components that interface with Nobel Biocare Internal Conical Connection implants. The subject device cover screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and are anodized to identify the prosthetic platform (NP and RP).

The compatible Nobel Biocare Internal Conical Connection prosthetic components (NP and RP platforms) include cover screws, healing abutments, temporary abutments esthetic abutments, straight multi-unit abutment, and angled multi-unit abutments.

All subject device implants and cover screws are individually packaged and are provided sterile.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

- engineering analysis demonstrates that the subject device implants are compatible with Nobel Biocare Internal Conical Connection prosthetic components (NP and RP platforms);
- non-clinical worst-case MRI review to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods, J.G. Delfino, and S. Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," *Journal of Testing and Evaluation*, Volume 49 (2): 783–795), based on the entire system including all variations (implant bodies, prosthetic components, and fixation screws) and material composition, and the rationale addressed parameters per the FDA guidance Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, including magnetically induced displacement force and torque;
- sterilization testing conducted to validate the gamma irradiation sterilization process to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VD_{max}^{25}, according to ISO 11137-1 and ISO 11137-2; bacterial endotoxin testing including *Limulus* amebocyte lysate (LAL) test according to ANSI/AAMI ST72 to demonstrate that all sterile product meets a limit of < 20 EU/device; and shelf life testing of samples after accelerated aging equivalent to five (5) years of real time aging according to ASTM F1980, with testing of the packaging sterile barrier;
- biocompatibility testing according to ISO 10993-5 (cytotoxicity) to demonstrate that the final finished subject device components (implants and cover screws) will be substantially equivalently biocompatible for their intended use;
- Surface treatment analysis by performing SEM and EDS testing conducted according to "Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Class II Special Controls Guidance Document for Industry and FDA Staff" and FDA Guidance Document "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions" to demonstrate the subject devices' surface does not contain residues from the production process;
- mechanical testing conducted according to ISO 14801:2016 and "Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Class II Special Controls Guidance Document for Industry and FDA Staff" to demonstrate the performance of the subject device implants and compatible OEM prosthetic components in comparison to primary predicate K142260;
- comparative surface area analysis considering the worst-case scenario for clinical placement (smallest implant and largest osteotomy per the approved drilling protocols), including total surface area, total surface area with simulated 3 mm of bone loss and, surface area of initial bone-to-implant contact to demonstrate substantial equivalence to the reference devices K163349 and K181850, and
- pullout testing comparing subject device implant to a reference device of similar size and surface treatment (K163349) considering the clinical worst-case scenario for clinical placement (smallest implant and largest osteotomy per the approved drilling protocols) to demonstrate substantial equivalence to the reference device.

Clinical testing literature data used to demonstrate substantial equivalence included:

- review of clinical literature data for primary predicate K142260 and reference predicate K163349 to demonstrate that gaps or distances between the implant collars and osteotomy bone, did not result in incomplete integration, bone recession, or loss and that the implant collar design and bone-to-implant area of the predicate and reference devices have shown consistent clinical safety and effectiveness,

with no negative outcome. In case of reference predicate K181850 the gap between implant collar and osteotomy bone did not result in incomplete integration, when adequately filled with bone grafting material. The table below shows the used literature.

Clinical Testing Literature Table

Number	Citation	Subject Device Design Feature	Implant	Study Design	Treatment concept	Clinical outcomes - Bone level changes	Relevance to NUVENTUS NV.C
1	Gultekin BA, Gultekin P, Leblebicioglu B, Basegmez C, Yalcin S. Clinical evaluation of marginal bone loss and stability in two types of submerged dental implants. Int J Oral Maxillofac Implants. 2013 May-Jun;28(3):815-23	Internal conical connection	K142260 NobelActive® Nobel Biocare AB. Nobel Replace Tapered (Nobel Biocare AB).	Prospective Clinical Trial	Healed site (3 months)	The cumulative implant survival rate was 100%. At the second-stage surgery, bone levels were similar between groups. One year after loading, mean crestal bone loss was 0.35 ± 0.13 mm for NobelActive implants and 0.83 ± 0.16 mm for NobelReplace implants, a significant difference.	Both implant systems had the same survival rates. NobelActive implants with a built-in platform switch and conical connection with back-tapered collar design achieved higher primary stability at insertion and less bone resorption after 15 months. Conical connection of NUVENTUS NV.C is compatible to NobelActive implants. Relevant design feature for subject device: The conical connection of NUVENTUS NV.C™ is compatible to NobelActive® implants. This article provides performance information based on the long-term data for three-dimensional marginal bone level, implant stability, and peri-implant health that is considered to be relevant to the subject device.
2	Kolinski ML, Cherry JE, McAllister BS, Parrish KD, Pumphrey DW, Schroering RL. Evaluation of a variable-thread tapered implant in extraction sites with immediate temporization: a 3-year multicenter clinical study. J Periodontol. 2014 Mar;85(3):386-94.	Internal conical connection	K142260 NobelActive® Nobel Biocare AB	Prospective Multicenter Clinical Study	Fresh extraction sockets	Thirty-five implants were evaluated at both implant insertion and 3-year follow-up. There was a slight decrease in mean bone level from -0.68 mm at implant insertion to -0.93 mm at the 6-month recall and then an increase of bone to -0.53 mm from the reference point at the 2-year follow-up (an average increase of 0.15 mm from implant insertion).	The results showed stable bone and soft tissue levels around this implant after 3 years in function, indicating that the implant can be used safely and effectively under the demanding conditions of immediate loading on implants placed in extraction sockets while also providing a high level of patient satisfaction. All implants were reported stable at the 6-month, 1-year, 2-year, and 3-year follow-ups. Relevant design feature for subject device: The conical connection of NUVENTUS NV.C™ is compatible to NobelActive® implants. This article provides performance information based on the long-term data for bone remodeling, survival rate, and soft tissue health that is considered to be relevant to the subject device.
3	Pozzi A, Agliardi E, Tallarico M, Barlattani A. Clinical and radiological outcomes of two implants with different prosthetic interfaces and neck configurations: randomized, controlled, split-mouth clinical trial. Clin Implant Dent Relat Res. 2014 Feb;16(1):96-106.	Internal conical connection	K142260 NobelActive® Nobel Biocare AB. Nobel Speedy Groovy, Nobel Biocare AB.	Randomized Controlled Trial	Healed site (6 months)	No implants and prosthesis failed. Survival rate was 100%. Marginal bone changes were statistically significantly different with better results for the internal conical connection: mean marginal bone loss (mm) (SD): 0.37 (0.23) for Nobel Active, vs 0.95 (0.56) for Nobel Speedy Groovy from baseline to 16 weeks (unloaded period).	Both implant designs (NobelActive K142260 and NobelSpeedy Groovy K160119 investigated provided successful results; however, the MBL was statistically significantly lower in the back-tapered neck configuration with conical connection of K142260 - equivalent internal conical connection, as NUVENTUS NV.C. Relevant design feature for subject device: The conical connection of NUVENTUS NV.C™ is compatible to NobelActive® implants. This article provides performance information based on the long-term data comparing clinical and radiological outcomes that is considered to be relevant to the subject device.
4	Li Manni L, Lecloux G, Rompen E, Aouini W, Shapira L, Lambert F. Clinical and radiographic assessment of circular versus triangular crosssection neck Implants in the posterior maxilla: A 1-year randomized controlled trial. Clin Oral Implants Res. 2020 Sep;31(9):814-824.	Triangular neck design	K163349 MIS V3 Conical Connection Dental Implant System MIS Implants Technologies Ltd. MIS C1 Dental Implant System.	Randomized Controlled Trial	Healed site (12 weeks)	No implant loss occurred within the follow-up period. The mean ± SD peri-implant proximal bone loss 1-year after loading was 0.22 ± 0.30 mm for triangular and 0.42 ± 0.67 mm for circular implants necks (p=0.25).	Circular and triangular (K163349) cross-section neck implants in the posterior maxilla were similar with respect to peri-implant bone changes. The implant neck design did not impact the pink aesthetic score and the patient satisfaction. Relevant design feature for subject device: Like the MIS V3, the NUVENTUS NV.C™ implant is designed with coronal flutes. This article provides performance information based on one-year data comparing peri-implant bone changes of circular versus triangular cross-section neck implants that is considered to be relevant to the subject device.

Number	Citation	Subject Device Design Feature	Implant	Study Design	Treatment concept	Clinical outcomes - Bone level changes	Relevance to NUVENTUS NV.C
5	Hurtgen A, Seidel L, Manni LL, Liegeois L, Lecloux G, Lambert F. Clinical and radiographic assessment of circular versus triangular cross-section neck implants in the posterior maxilla: Five-year follow-up of a randomized controlled trial. Clin Oral Implants Res. 2023 Jul;34(7):698-706.	Triangular neck design	K163349 MIS V3 Conical Connection Dental Implant System MIS Implants Technologies Ltd. MIS C1 Dental Implant System.	Randomized Controlled Trial	Healed site placement (12 weeks)	No implant loss occurred during the 5-year follow up period. The mean ± SD proximal bone remodeling after 5 years reached 0.38 ± 0.39 mm for the circular design and 0.29 ± 0.58 mm for the triangular design (p = .49).	The 5-year evaluation of the triangular neck implants showed similar results to the circular neck implants. Relevant design feature for subject device: The 5year clinical data for the predicate with initial gap between implant collar and osteotomy bone showed low rates of peri-implant bone loss and occurrence of periodontitis. This article provides relevant performance information based on assessing the peri-implant bone stability and the peri-implant soft tissue conditions over 5-years and is considered to be relevant to the subject device.
6	Tokuc B, Kan B. The effect of triangular cross-section neck design on crestal bone stability in the anterior mandible: A randomized, controlled, splitmouth clinical trial. Clin Oral Implants Res. 2021 Oct;32(10):1241-1250.	Triangular neck design (TN)	K163349 MIS V3 Conical Connection Dental Implant System MIS Implants Technologies Ltd. MIS C1 (circular neck, RN) Dental Implant System.	Randomized Controlled Trial	Healed site (3 months)	No implant loss was observed during the follow-up period. The mean ± SD proximal crestal bone loss one year after loading was 0.58 ± 0.36 mm for TN and 0.91 ± 0.59 mm for RN ($p < 0.01$).	The presentation of stable peri-implant soft tissue and crestal bone levels in both circular and triangle (K163349) neck groups. Relevant design feature for subject device: This article provides performance information comparing crestal bone loss and buccal bone thickness around a triangular cross-section neck to a round neck design over a one-year period of follow-up. Stable peri-implant soft tissue and crestal bone levels were observed for both groups, which are considered to be relevant to the subject device.
7	Chu SJ, Östman PO, Nicolopoulos C, Yuvanoglu P, Chow J, Nevins M, Tarnow DP. Prospective Multicenter Clinical Cohort Study of a Novel Macro Hybrid Implant in Maxillary Anterior Postextraction Sockets: 1-Year Results. Int J Periodontics Restorative Dent. 2018;38(Suppl):s17-s27.	Narrow coronal segment of the implant	K181850 Inversa Implants, Southern Implant (Pty), Ltd	Prospective Multicenter Cohort Study	Fresh extraction sockets	No implants failed during an average healing period of one year. Marginal bone level changes: A tooth to-implant interdental bone crest distance and dimension of 2.3 to 2.6 mm was reached; it was also sustained at the 1-year follow-up. No marginal bone loss was evaluated, as bone graft was used.	As the Inversa implants have an even larger gap between implant collar and bone, they can be considered as the clinical worst-case. Predicate K181850 implants were considered to be safe and effective in this study when the gap was filled with bone grafting material. Relevant design feature for subject device: As the Inversa implants have an even larger and circumferential gap between implant collar and bone, they can be considered as the clinical worst-case. Predicate This article provides relevant performance information, based on one-year data for a macro hybrid implant placed into maxillary anterior post extraction sockets, that is considered to be a clinical worst-case to the subject device.
8	Chu SJ. Inverted body-shift concept in macroimplant design to enhance biologic and esthetic outcomes: A clinical report. J Prosthet Dent. 2021 Dec;126(6):720-726.	Narrow coronal segment of the implant	K181850 Inversa Implants, Southern Implant (Pty), Ltd	Clinical report	Fresh extraction sockets	At 6 months post surgery, a tooth to-implant distance at the distal aspect of the central incisor implant between the central and lateral incisors was 1.8 mm. No measurements of marginal bone loss as bone grafting was performed.	Reduction of the load on the buccal bone, as our selected predicate devices prove the benefit of such designs regarding clinical long-term performance and crestal bone maintenance. Relevant design feature for subject device: As the Inversa implants have an even larger and circumferential gap between implant collar and bone, they can be considered as the clinical worst-case. Predicate Inversa implants showed good clinical performance and crestal bone maintenance during the study when the gap was filled with bone grafting material. This article provides relevant performance information based on the data, which is considered to be a clinical worst-case to the subject device.

Number	Citation	Subject Device Design Feature	Implant	Study Design	Treatment concept	Clinical outcomes - Bone level changes	Relevance to NUVENTUS NV.C
9	Gluckman H, Pontes CC, Chu S. Immediate Tooth Replacement in the Esthetic Zone with the Socket Shield Technique and a Novel Body-Shift Implant: A Pilot Study with Up to 3 Years of Follow-up. Int J Periodontics Restorative Dent. 2023 Oct 24;(7):s107-s117.	Narrow coronal segment of the implant	K181850 Inversa Implants, Southern Implant (Pty), Ltd	Pilot study	Fresh extraction sockets	Patients were followed up for 12 to 39 months (mean 18.1±8.2 months). The survival rate was 100%. Mean interproximal marginal bone loss was -0.4±0.5mm	As the Inversa implants have an even larger gap between implant collar and bone, they can be considered as the clinical worst-case. Predicate K181850 implants were considered to be safe and effective in this study. Relevant design feature for subject device: As the predicate Inversa implants have an even larger and circumferential gap between implant collar and bone, they can be considered as the clinical worst-case. The predicate device showed good clinical performance and crestal bone maintenance during the study when the gap was filled with bone grafting material. This article provides relevant performance information for marginal bone loss for the predicate device, which is considered to be a clinical worst-case to the subject device.
10	O'Hooley, Dominic Brenden, Costa Nicolopoulos, Mark Worthing, Petros Yuvanoglu, Fotis Melas, and Peter Fairbairn. "Outcomes of a One Year, Retrospective Single-Arm Cohort Study Using both a Novel Body-Shift Implant Design with a Novel Alloplastic Particulate Grafting Material in Immediate Extraction Sockets." (2023).	Narrow coronal segment of the implant	K181850 Inversa Implants, Southern Implant (Pty), Ltd	Retrospective Single-Arm Cohort Study	Fresh extraction sockets	In this study, only the new buccal bone and the PES of the soft tissue are measured. No measurements of marginal bone loss as bone grafting was performed.	The relatively narrow coronal portion of the Inversa implant along with the use of bone grafting material appears to have improved bone regeneration in the critical aesthetic coronal zone for enhanced tissue stability. As the Inversa implants have an even larger gap between implant collar and bone, they can be considered as the clinical worst-case. Predicate K181850 implants were considered to be safe and effective in this study. Relevant design feature for subject device: As the Inversa implants have an even larger and circumferential gap between implant collar and bone, they can be considered as the clinical worst-case. Predicate Inversa implants were considered by the investigators to be safe and effective in this study, as the predicate devices showed good clinical performance and crestal bone maintenance during the study. This article provides relevant performance information for stability of the predicate device while using bone augmentation material placed in the circumferential jumping gaps of the extraction sockets.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

The primary predicate device K142260 is in support of substantial equivalence for the overall implant design, range of implant lengths, and material. The primary predicate device K142260 is in support of substantial equivalence specifically regarding the implant diameters and their associated indications for use, and the prosthetic connection configuration for the NUVENTUS NV.C™ subject devices.

The reference device K163349 is in support of substantial equivalence specifically with regard to the external implant macro geometry, the material, and the external surface modification. The reference device K181850 is in support of substantial equivalence specifically with regard to coronal thread engagement with the prepared osteotomy.

The Indications for Use Statement (IFUS) for the subject device includes language concerning placement in the upper or lower jaw, placement into immediate function, and support for single unit and multiple unit restorations. This language conveys the same indications as is stated in the IFUS in K142260, K163349, K181850 and K071370. Slight differences in the language of the subject and predicate Indications for Use Statements do not affect the intended use of the subject devices.

Subject Device Dental Implants and Cover Screws

The external features of the subject device implants have similar designs compared to the primary predicate device implants cleared in K142260. Both the subject and primary predicate devices are externally threaded endosseous dental implants made from similar materials. The subject device implant body diameters range from 3.5 mm to
5.0 mm, which is within the range of implant diameters cleared in K142260. The subject device implant lengths range from 8 mm to 15 mm, which is within the range of the implant lengths cleared in K142260.

The subject device implants have internal conical abutment connections of equivalent sizes and design as compared to the implants cleared in K142260. The subject device implants with the NP prosthetic platform have an outer diameter of 3.5 mm or greater, which is equivalent to the outer diameter of the reference devices (NP 3.5 Conical Connection) in K142260.

The subject devices are provided sterile by subjecting the packaged product to gamma radiation, which is equivalent to the method used to sterilize the reference devices cleared in K163349.

The subject device implants have external surface geometry roughened by grit blasting, resulting in surface that is similar to that of the reference device implants cleared in K163349. The subject device implants and cover screws are manufactured from the same titanium alloy (Ti-6Al-4V, ASTM F136) as those cleared in K163349. The subject device cover screws are colored through a process of titanium anodization, which is equivalent to the process utilized to add color to reference prosthetic components cleared in K163349. Additionally, substantial equivalence with regard to biocompatibility is supported by biocompatibility testing per ISO 10993.

The 4.3 mm and 5.0 mm diameter subject device implants have external surface modifications in which flutes are cut into the coronal end of the implant. This feature is similar to features found on

implants cleared in K163349 where the outer diameter of the implant (and, therefore, engagement with the bone) is reduced compared with the fully threaded section. The coronal features of the subject device implants engage the bone of the osteotomy to a greater extent compared with the bone engagement of implants cleared in K181850. The reference implants in K181850 have little or no contact with the bone in the coronal region when the implant is placed to its full seating depth. Additionally, substantial equivalence with regards to surface area and bone to implant contact is supported by comparative surface area analysis and pullout testing.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, encompass the same range of physical dimensions, have similar technological characteristics, are made of the same or similar materials, and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Implant and Cover Screw Table of Substantial Equivalence

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Substantial Equivalence**
	K233081 **Infinitum Eta Ltd.** **NUVENTUS NV.C™ Dental Implant System**	**K142260** **NobelActive®** **Nobel Biocare AB**	**K163349** **MIS V3 Conical Connection Dental Implant System MIS Implants Technologies Ltd.**	**K181850** **Inversa Implants Southern Implant (Pty) Ltd.**	
Indications for Use Statement	NUVENTUS NV.C™ Dental Implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. NUVENTUS NV.C™ Dental Implants may 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. NUVENTUS NV.C™ Dental Implants are compatible for use with the following prosthetic interfaces. **Implant System Prosthetic Compatibility** / **Platform Size/Designation** Nobel Biocare Internal Conical Connection (CC) — NP CC; RP CC	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive® 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are indicated for single unit restorations only.	MIS V3 Conical Connection Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	Inversa Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Inversa Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.	Similar indications, slightly different wording – no additional risk for substantial equivalence
Reason for Predicate Device	Not applicable	Implant design including length range, diameters, prosthetic connection, and Indications for Use limitations; materials; manufacturing; sterilization	Implant design including external macro geometry; material; external surface modification	Engagement of the coronal features with the bone of the osteotomy	n/a
Product Codes	DZE, NHA	DZE, NHA	DZE, NHA	DZE	Identical product codes
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Identical intended use
Implant Body Design	Straight with apical taper, externally threaded, facial/lingual grooved flutes	Expanding taper, externally threaded, drilling blades on apex	Tapered, externally threaded, three-way cutaway longitude implant axis at the cervical part of the implant	Fully threaded, tapered, root-form dental implants with a design feature known as body shift, where the body design of the implant has a narrow, straight coronal portion with an increased maximum diameter midway down the length of the implant tapering toward the apex. The body of the implant includes two thread types (square and V-shaped) that transition in the middle of the implant body.	Similar screw-type implant design with differences in the coronal part of the implants, differences were assessed with comparative nonclinical testing, literature review, and labeling mitigations
Prosthetic Interface Connections	Internal conical connection with internal hexagon anti-rotational engagement	Internal Conical Connection with internal hexagon anti-rotational engagement	Internal conical connection with 3- or 6-sided anti-rotational index.	External hex and deep conical double hex anti-rotational engagement	Identical to the primary predicate. Subject and predicate devices all have internal conical connections. The subject device conical connection was reverse engineered from the connection of the primary predicate.
Body/Platform Diameters	Body Ø, mm / Platform Name (Seating Ø, mm) 3.5 / NP (3.0) 4.3 / NP (3.0); 5.0 / RP (3.4)	Body Ø, mm / Platform Name (Seating Ø, mm) 3.0 / 3.0 (2.5) 3.5 / NP (3.0) 4.3, 5.0 / RP (3.4) 5.5 / WP (4.4)	 3.3 / NP (2.75) 3.9, 4.3, 5.0 / SP (3.15)	 Deep Conical 3.6 coronal – 4.5 apical (max) / 3.1 3.6 coronal – 5.0 apical (max) / 3.1 4.0 coronal – 5.0 apical (max) / 3.1	Similar. Body/Platform diameters of subject device are in the range of predicate devices
Lengths, mm	8.0 – 15, all body diameters	Ø 3.0 – 10-15; Ø 3.5, 4.3, 5.0 – 8.5-18; Ø 5.5 – 7.0-15	Ø 3.3 – 10-16; All other body diameters – 8-16	11.5, 13, 15, 18	Similar. Subject implant lengths are in the same range as predicate devices
Implant Material	Titanium alloy, ASTM F136	Unalloyed titanium	Titanium alloy, ASTM F136	Unalloyed titanium	Identical. Subject device and reference predicate #1 have the same material

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Substantial Equivalence
	K233081 **Infinitum Eta Ltd.** **NUVENTUS NV.C™ Dental Implant System**	**K142260** **NobelActive®** **Nobel Biocare AB**	**K163349** **MIS V3 Conical Connection Dental Implant System MIS Implants Technologies Ltd.**	**K181850** **Inversa Implants Southern Implant (Pty) Ltd.**	
Implant Endosseaous Surface	Blasted with resorbable media and acid etched	TiUnite	Sand blasted and acid etched	Grit blasted	Similar surfaces with the same function
Cover Screw Materials	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136	*Not stated in 510(k) Summary*	Identical
Cover Screw Coloration	Titanium anodization	*N/A*	Titanium anodization	*Not stated in 510(k) Summary*	Identical to the reference device
How Provided					
Implants	Sterile by gamma irradiation	Gamma irradiation	Radiation	Gamma irradiation	Identical
Cover Screws	Sterile by gamma irradiation	*Not stated in 510(k) Summary*	*Not stated in 510(k) Summary*	*Not stated in 510(k) Summary*	
Usage	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Identical