



December 23, 2025

Paragon Implant Mfg., LLC
Renee Bennett
Regulatory Affairs Manager
27030 Malibu Hills Road
Calabasas, California 91301

Re: K250476

Trade/Device Name: NizPlant Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 25, 2025
Received: November 28, 2025

Dear Renee Bennett:

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,

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

Submission Number (if known)

K250476

Device Name

NizPlant Dental Implant System

Indications for Use (Describe)

NizPlant Implants are a one-piece implant or two-piece assembly for single-stage surgical procedures intended for surgical implantation in edentulous or partially edentulous mandibles or maxilla for attachment of complete denture prostheses, or for fixed or removable bridgework for multi-unit tooth replacement.

NizPlant Implants can be indicated for immediate function when initial implant stability has been achieved and with appropriate occlusal loading.

Short (<9mmL) Implants: Indicated for multiple-unit restorations of partially or fully edentulous mandibles and maxillae where vertical bone volume is limited.

The NizPlant Implants have a 2.5mmD internal hex within its most coronal portion for the insertion tool placement used in the full seating of the NizPlant Implant in the osteotomy. Implant placement, which is designed to receive multiple abutment variations, expands its restorative options allowing for the implant to be used for:

- Support of attachment-retained overdentures
- Support of screw-retained prostheses

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
Paragon Implant Mfg., LLC
NizPlant Dental Implant System
December 23, 2025

Manufacturer Name: Paragon Implant Mfg., LLC
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Telephone (818) 475-4675

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Device Name and Classification:

Trade/Proprietary Name	NizPlant Dental Implant System
Common Name	Implant, Endosseous, Root-Form
Regulation Number	21 CFR § 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code(s)	DZE (Primary) NHA (Secondary)

Legally Marketed Predicate Device(s):

Primary Predicate Device (DZE, NHA – Implants, Abutments)	K090234 (Spectra-System Dental Implants 2008), Implant Direct LLC
Primary Reference Device (DZE - Implants)	K202344 (TiUltra Implants and Xeal Abutments), Nobel Biocare AB
Reference Device (DZE - Implants)	K232418 (Single Platform SP1 Implant System), Southern Implants (Pty) Ltd
Reference Device (DZE - Implants)	K222457 (Provata Implant System), Southern Implants (Pty) Ltd
Reference Device (DZE - Implants)	K223814 (Genesis ACTIVE Implant System), Keystone Dental Inc.
Reference Device (DZE - Implants)	K023113 (Replace TiUnite Endosseous Implant (Replace Select TC), Nobel Biocare USA, Inc.
Reference Device (DZE - Implants)	K080633 (ScrewIndirect Dental Implants), Implant Direct, LLC
Reference Device (DZE - Implants)	K251938 (GEN5 and GEN5+ Dental Implant System) Paragon Implant Mfg., LLC

Device Description:

The NizPlant Dental Implant System consists of a root form Endosseous dental implant and various other prosthetic/restorative components (medical devices) to plan, implant, and support restorations for edentulous patients.

NizPlant Implants are a one-piece implant or two-piece assembly for single-stage surgical procedures intended for surgical implantation in edentulous or partially edentulous mandibles or maxilla for attachment of complete denture prostheses, or for fixed or removable bridgework multi-unit tooth replacement.

The top one-third of the NizPlant Implant body has a straight machined neck that is placed in crestal bone. The depth gauge lines at 1mm, 2mm and 2.5mm from the top of the straight machined neck portion of the implant body facilitate the placement level with the crest of the ridge or 1mm above the crest of the ridge. Above the straight neck of the implant body is a dual-function platform which acts as an overdenture or a multi-unit abutment.

The lower two-thirds of the Implant is tapered with double-lead progressively deeper reverse buttress threads for increased bone contact. The two full-length cutting grooves are self-tapping and extend over the tapered portion of the implant's body.

The NizPlant dental implant body is available in six diameter sizes. This assortment of implants in various diameters and lengths are to be matched with an extensive componentry offering. NizPlant Implants lengths are measured from the apex of the implant to the midpoint of the gold anodized zone, that is to the base of the abutment portion of the NizPlant Implant.

Body Diameters	Platform Diameters	External Platform Diameter	Lengths
3.0mm	3.5mm	3.9mm	9mm, 11mm, 12.5mm, 14mm
3.7mm	3.5mm	3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm
4.2mm	3.5mm	3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm
4.7mm	3.5mm	3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm
5.2mm	3.5mm	3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm
5.7mm	3.5mm	3.9mm	7mm, 9mm, 11mm, 12.5mm, 14mm

NizPlant Implants have a portion of their coronal surface anodized a gold color. The gold color aids aesthetically as it is the portion that extends transmucosal from bone level, through to the oral cavity by masking of the underlying color of the non-anodized standard titanium grey. Due to its length, the 7mmL and 9mmL implants have one less circumferential groove and are replaced with an additional external thread to increase fixation within the bone.

NizPlant Implants are specifically designed with a combination of 0.5mm and/or the 1mm height circumferential grooves above the blasted implant surface (7mmL - 9mmL implant does not have the additional 0.5mm circumferential score line). These visual demarcations aid the clinician by providing the option for vertical height variability during placement. For restorations where the vertical position of the surrounding bone and/or soft tissue dictate that, part of the implant's anodized portion within the

straight machined neck of the NizPlant Implant body may remain supra-crestal after placement (in addition to the 3mm prosthetic option of the dual function platform).

The NizPlant Implants are anodized a gold color with a portion of the Implant going through a surface treatment (blasting) to create a microtextured surface roughness. These implants (and the devices included in the packaging) are sold sterile. The NizPlant Implants are manufactured from titanium alloy (Ti-6Al-4V ELI) complying with standard ASTM F136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant.

The various devices included in the NizPlant Implant System (such as Endosseous dental implant abutments, cover screws, fixation screw, etc.) and various other prosthetic/restorative components used to plan, implant, and support restorations for fully and partially edentulous patients are offered in compatible platform dimensions to enable a complete dental restoration.

The Cover Screws are available in 5.5mm diameter with a platform diameter of 3.5mm. They are manufactured from titanium alloy (Ti-6Al-4V ELI) complying with standard ASTM F136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant).

The Titanium Non-Engaging Temporary Abutments are available in 5.0mm diameter with a platform diameter of 5.5mm. This is a straight configuration. They are manufactured from titanium alloy (Ti-6Al-4V ELI) complying with standard ASTM F136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant) and anodized a gold color.

The Non-Engaging Angled Screw Channel (ASC) Abutments are available in 4.7mm diameter with a platform diameter of 5.0mm and length of 0.5mm. This is a straight configuration. They are manufactured from titanium alloy (Ti-6Al-4V ELI) complying with standard ASTM F136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant) and anodized a gold color.

The Straight Multi-Unit (MUA) Abutments are available in 3.2mm diameter with a platform diameter of 4.8mm and length of 3.2mm. This is a straight configuration. They are manufactured from titanium alloy (Ti-6Al-4V ELI) complying with standard ASTM F136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant) and anodized a gold color.

The Fixations Screws are all manufactured from titanium alloy (Ti-6Al-4V ELI) complying with standard ASTM F136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant).

Indications for Use Statement:

NizPlant Implants are a one-piece implant or two-piece assembly for single-stage surgical procedures intended for surgical implantation in edentulous or partially edentulous mandibles or maxilla for attachment of complete denture prostheses, or for fixed or removable bridgework for multi-unit tooth replacement.

NizPlant Implants can be indicated for immediate function when initial implant stability has been achieved and with appropriate occlusal loading.

Short (<9mmL) Implants: Indicated for multiple-unit restorations of partially or fully edentulous mandibles and maxillae where vertical bone volume is limited.

The NizPlant Implants have a 2.5mmD internal hex within its most coronal portion for the insertion tool placement used in the full seating of the NizPlant Implant in the osteotomy. Implant placement, which is designed to receive multiple abutment variations, expands its restorative options allowing for the implant to be used for:

- Support of attachment-retained overdentures
- Support of screw-retained prostheses

Equivalence to Marketed Devices:

The indications for use are the same as the predicate except the subject device is for multi-unit tooth replacement while the predicate is single-tooth and multi-tooth replacement. The subject indicates short implants for where vertical bone is limited.

The proposed NizPlant Dental Implant System consists of root form Endosseous dental implants, Endosseous dental implant abutments, and various other prosthetic/restorative components (medical devices) to plan, implant, and support restorations for edentulous patients.

The threaded root form Implants are manufactured from Ti-6Al-4V ELI per complying with standard ASTM F136-13). Both the proposed and predicate device (K090234) are anodized and blasted with a soluble blast media to create a microtextured surface roughness below the bone level region of the Implant.

The subject and reference predicate(s) have a similar size range for the machined and/or anodized Endosseous collars.

The lower tapered portion of the proposed device has two cutting flutes which is identical to the predicate device (K090234).

The body diameters of the proposed Implants are similar to those of the predicate device (K090234). The only exception is that the proposed Implants are available in larger body diameter sizes at 5.2mm and 5.7mm.

The lengths of the proposed Implants are similar to those of the predicate device (K090234). The proposed Implants have a smaller length at 7mm whereas the predicate has the smallest at 8mm. Also, the proposed Implants have the largest length at 14mm whereas the predicate has their largest at 13mm.

The platform of the proposed device is identical to the predicate device (K090234).

The additional devices provided inside the packaging differ from the proposed device and predicate device (K090234).

Both the proposed device and the predicate device (K090234) is packaged in a vial and cap with labels. The Implants and Cover Screw of the proposed and predicate device (K090234) are single-use and delivered sterile (gamma irradiated) while all other components are single-use and delivered non-sterile and sterilized by the end user via steam sterilization per the Instructions for Use (IFU).

Table 1. Substantial Equivalence Comparison In Tabular Format outlines the Intended Use and Technological Characteristics of each predicate and reference devices.

Performance Data:

- Non-clinical data submitted demonstrates substantial equivalence to the predicate and reference devices and/or passing validation criteria included:
- Chemical characterization and biocompatibility validations per ISO 10993 and ISO 7405
- Sterilization validation for all devices sold sterile per ANSI/AAMI/ISO 11137-2/.
- Cleaning and sterilization validations for all devices sold non-sterile per ISO 17664-1, AAMI TIR12, and ISO 17665.
- Simulation and Physical MRI validations per ASTM F2052, ASTM F2119, ASTM F2182, and ASTM F2213.
- Accelerated aging per ASTM F1980-21 was conducted on cap and vial packaging and immediately followed by shelf-life testing of the sterile barrier via membrane filtration sterility of the interior of the vial according to ISO 11737-2.
- Simulated transportation conditioning was conducted per ASTM D4169 and ASTM F7386.
- Surface characterization of the anodized surface including surface area, surface roughness, surface thickness confirms that the anodization does not affect the surface roughness of the implant collar compared to the machined surface, and the surface characteristics.
- Surface treatment analysis of the blasted surface by performing SEM (Scanning Electron Microscopy) and EDS (Energy Dispersive X-ray Spectroscopy) 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 validate cleaning protocols after blasting.
- Endotoxin testing was conducted for endotoxins using the kinetic turbidimetric and chromogenic techniques in accordance with ANSI/AAMI ST72:2019, USP <161>, and USP <85>.
- Testing of short implants was conducted in silico [using SolidWorks 2023 (Dassault Systèmes)] to evaluate available implant surface area (SA) and initial bone-to-implant contact (BIC) for bone level and 1mm supracrestal placement, before and after 3mm of resorption.
- Pullout load testing was conducted to evaluate indirect BIC using bone level placement. No clinical data was included in this submission.

Conclusion:

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

Table 1. Substantial Equivalence Comparison in Tabular Format

TABLE 1: SUBSTANTIAL EQUIVALENCE COMPARISON IN TABULAR FORMAT

Characteristic	Proposed Device: (K250476)	Primary Predicate Device: (K090234)	Reference Device: (K202344)	Reference Device: (K232418)	Reference Device: (K222457)	Reference Device: (K223814)	Reference Device: (K023113)	Reference Device: (K080633)
Manufacturer/ Device Applicant	Paragon Implant Mfg, LLC	Implant Direct LLC	Nobel Biocare AB	Southern Implants (Pty) Ltd	Southern Implants (Pty) Ltd	Keystone Dental Inc.	Nobel Biocare USA, Inc.	Implant Direct. LLC
Image								
Trade/Device Name	NizPlant Dental Implant System	Spectra-System Dental Implants 2008	TiUltra Implants and Xeal Abutments	Single Platform SP1 Implant System	Provata Implant System	Genesis ACTIVE Implant System	Replace TiUnite Endosseous Implant (Replace Select TC)	ScrewIndirect Dental Implants
Regulation Number	21 C.F.R. § 872.3640 (Endosseous dental implants)	21 C.F.R. § 872.3640 (Endosseous dental implants)	21 C.F.R. § 872.3640 (Endosseous dental implants)	21 C.F.R. § 872.3640 (Endosseous dental implants)	21 C.F.R. § 872.3640 (Endosseous dental implants)	21 C.F.R. § 872.3640 (Endosseous dental implants)	21 C.F.R. § 872.3640 (Endosseous dental implants)	21 C.F.R. § 872.3640 (Endosseous dental implants)
Classification	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Class II
Primary Product Code	DZE	DZE	DZE	DZE	DZE	DZE	DZE	DZE
Secondary Product Code	NHA	NHA	N/A	N/A	N/A	NHA	NHA	N/A
Reason for Predicate/Reference	N/A	<ul style="list-style-type: none"> • Same: <ul style="list-style-type: none"> ○ General design ○ Implant Platform ○ Cutting Flutes ○ Sterility 	Collar design, 2mm anodized machined endosseous collar with horizontal grooves	Collar design, 3mm machined endosseous collar	Collar design, 3mm machined endosseous collar	Collar design, 1-2mm anodized machined	Collar design, 3mm machined collar	Body diameter of 3.0mm and threaded lengths of 7.0mm up to 12mm

Characteristic	Proposed Device: (K250476)	Primary Predicate Device: (K090234)	Reference Device: (K202344)	Reference Device: (K232418)	Reference Device: (K222457)	Reference Device: (K223814)	Reference Device: (K023113)	Reference Device: (K080633)
		<ul style="list-style-type: none"> ○ Sterilization ○ Usage ○ Materials ○ Surface ● Differences: <ul style="list-style-type: none"> ○ Indications of subject devices is for multi-unit tooth replacement and predicate is single-tooth and multi-tooth; subject has short implants indicated for where vertical bone is limited ○ Body diameters are similar with subject range 3.0mm – 5.7mm and predicate range 3.0mm – 4.7mm ○ Implant Lengths are similar with subject range 7mm – 14mm and predicate range 8.0mm – 13mm 				endosseous collar		
Indications for Use	NizPlant Implants are a one-piece implant or two-piece assembly for	The Spectra-System Dental Implant 2008 system is comprised of dental implant	NobelActive TiUltra implants are endosseous implants intended to be	The Single Platform SP1 Implant	The Provata Implant System is	The Genesis ACTIVE Implant	Replace Select TC implant restorations range from	ScrewIndirect Narrow Dental Implants are implants for

Characteristic	Proposed Device: (K250476)	Primary Predicate Device: (K090234)	Reference Device: (K202344)	Reference Device: (K232418)	Reference Device: (K222457)	Reference Device: (K223814)	Reference Device: (K023113)	Reference Device: (K080633)
	<p>single-stage surgical procedures intended for surgical implantation in edentulous or partially edentulous mandibles or maxilla for attachment of complete denture prostheses, or for fixed or removable bridgework for multi-unit tooth replacement.</p> <p>NizPlant Implants can be indicated for immediate function when initial implant stability has been achieved and with appropriate occlusal loading.</p> <p>Short (<9mmL) Implants: Indicated for multiple-unit restorations of partially or fully edentulous mandibles and maxillae where</p>	<p>fixtures and prosthetic devices that compose a one- or two-piece implant system. The Dental Implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single-tooth or multiple-tooth restorations, recognizing bone stability and appropriate occlusal load requirements.</p>	<p>surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function.</p> <p>NobelActive TiUltra implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique.</p> <p>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.</p> <p>NobelActive TiUltra 3.0 implants are indicated for single-unit restorations</p>	<p>System is 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. The Single Platform SP1 Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved.</p> <p>The Single Platform SP1</p>	<p>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. The Provata Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved.</p> <p>The intended use for the Ø3.30 Provata</p>	<p>System is intended for use in single-stage or two-stage surgical procedures for replacing single or multiple missing teeth in partially or fully edentulous mandibles and maxillae. The Genesis ACTIVE Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis ACTIVE implants are</p>	<p>single tooth to fixed-removable full dental arch overdenture applications to restore chewing function. This can be achieved with 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. Implants allow also for bi-cortical anchorage in cases of reduced bone density to obtain high initial stability.</p>	<p>single-stage surgical procedures intended for use in partially or fully edentulous mandibles and maxillae, in support of complete or partial denture prostheses or as a terminal or intermediary attachment for fixed or removable bridgework via interface with copings. These implants are intended for immediate loading for support of splinted multiple tooth restorations, provided initial implant stability and appropriate occlusal load requirements are met.</p>

Characteristic	Proposed Device: (K250476)	Primary Predicate Device: (K090234)	Reference Device: (K202344)	Reference Device: (K232418)	Reference Device: (K222457)	Reference Device: (K223814)	Reference Device: (K023113)	Reference Device: (K080633)
	<p>vertical bone volume is limited.</p> <p>The NizPlant Implants have a 2.5mmD internal hex within its most coronal portion for the insertion tool placement used in the full seating of the NizPlant Implant in the osteotomy. Implant placement, which is designed to receive multiple abutment variations, expand its restorative options allowing for the implant to be used for:</p> <ul style="list-style-type: none"> • Support of attachment-retained overdentures • Support of screw-retained prostheses 		<p>only. NobelReplace CC TiUltra NobelReplace CC TiUltra implants are endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The NobelReplace CC TiUltra implants are indicated for single or multiple unit restorations. The NobelReplace CC TiUltra implants can be used in splinted or nonsplinted 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.</p>	<p>implants in lengths 20, 22 and 24 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.</p>	<p>implants is limited to replacement of maxillary and mandibular lateral and central incisors.</p> <p>The 12° angled Co-Axis Provata Implants are intended to only be used with straight abutments.</p>	<p>intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established, and appropriate occlusal loading is applied.</p> <p>All digitally designed custom abutments for use with Genesis ACTIVE Implant</p>		

Characteristic	Proposed Device: (K250476)	Primary Predicate Device: (K090234)	Reference Device: (K202344)	Reference Device: (K232418)	Reference Device: (K222457)	Reference Device: (K223814)	Reference Device: (K023113)	Reference Device: (K080633)
			<p>NobelParallel CC TiUltra NobelParallel CC TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting replacements to restore patient esthetics and chewing function. NobelParallel CC TiUltra implants are indicated for single or multiple restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical techniques in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants with <7mm length are for delayed loading only when appropriate</p>			<p>System implants are to be sent to a Keystone Dental validated milling center for manufacture.</p> <p>The KDG- Osteon Precision Milled Suprastructure is indicated for attachment to the Genesis ACTIVE Multi- Unit abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The KDG-Osteon Precision Milled Suprastructure is intended for attachment to</p>		

Characteristic	Proposed Device: (K250476)	Primary Predicate Device: (K090234)	Reference Device: (K202344)	Reference Device: (K232418)	Reference Device: (K222457)	Reference Device: (K223814)	Reference Device: (K023113)	Reference Device: (K080633)
			stability has been achieved.			a minimum of two (2) abutments.		
General Design	Threaded Root form implant	Threaded Root form implant	Threaded Root form implant	Fully threaded tapered root-form dental implants	Fully threaded tapered root-form dental implants	Threaded Root form implant	Threaded Root form implant	Threaded Root form implant
Body Diameters	3.0mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm	3.0mm, 3.7mm, 4.7mm	NobelActive TiUltra 3.0, 3.5, 4.3, 5.0, 5.5mm NobelReplace CC TiUltra 3.5, 4.3, 5.0mm NobelParallel CC TiUltra 3.75, 4.3, 5.0, 5.5mm	3.5, 4.0 and 5.0 mm	3.30 mm	3.5, 3.8, 4.5, 5.5 mm	3.5, 4.0 mm	3.0mm
Implant Lengths	7mm, 9mm, 11mm, 12.5mm, 14mm	8.0mm, 10mm, 11.5mm, 13mm	NobelActive TiUltra 7.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm NobelReplace CC TiUltra Externa : 7.5, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm 8.0, 10.0, 11.5, 13.0, 16.0mm NobelParallel CC TiUltra 6.5, 8.0, 9.5, 11.0, 12.5, 14.5, 17.5mm	For Ø3.5 implants: 8, 10, 11.5, 13, 16, 18, 20 mm; For Ø4.0 implants: 8, 10, 11.5, 13, 16, 18, 20, 22, 24 mm; For Ø5.0 implants: 8, 10, 11.5, 13, 16, 18 mm	8.5, 10, 11.5, 13, 15, 18 mm	For Ø 3.5: 10, 11.5, 13, 16 mm; For Ø 3.8: 8.5, 10, 11.5, 13, 16 mm; For Ø 4.5: 8.5, 10, 11.5, 13, 16 mm; For Ø 5.5: 8.5, 10, 11.5, 13 mm	For Ø 3.5: 10, 13, 16, 18 mm For Ø 4.0: 10, 13, 16, 18 mm	8mm, 10mm, 13mm, 16mm
Implant Platform	3.9mm (external radial profile) 3.5mm (internal hex)	3.9mm (external radial profile)	Internal conical connection with hex interface	For Ø3.5 implants: 3.30 mm;	3.10 mm for 0° implant, 3.0 mm for 12° implant	3.2mm	For Ø 3.5: mm For Ø 4.0: 4.3 mm	5.0mm

Characteristic	Proposed Device: (K250476)	Primary Predicate Device: (K090234)	Reference Device: (K202344)	Reference Device: (K232418)	Reference Device: (K222457)	Reference Device: (K223814)	Reference Device: (K023113)	Reference Device: (K080633)
				For Ø4.0 implants: 3.80 mm; For Ø5.0 implants: 4.50 mm				
Cutting Flutes	Double (2)	Double (2)	Not available	Not available	Not available	Not available	Not available	Not available
Connection Type	Internal hex	Internal truncated triangle	Internal hex	Internal Cone and Hex (SP1)	Internal Hex	Hex Internal interface with coronal conical taper	Not available	Not available
Implant Assembly	Implant and Cover Screw	Implant, Carrier/Transfer, and Comfort Cap	Not available	Not available	Not available	Not available	Not available	Implant, Carrier/Transfer, Extender, and Comfort Cap
Sterility	Implants and Cover Screws supplied sterile; All other devices supplied non-sterile. Devices steam sterilized (when applicable) by end user as per Instructions for Use (IFU)	Supplied sterile; comfort cap and carrier/transfer sterilized by end user when used as abutments.	Provided sterile	Provided sterile	Provided sterile	Provided sterile	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation	Gamma Radiation (SAL 10 ⁻⁶)	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use
Materials	Titanium 6AL-4V ELI	Titanium 6AL-4V ELI	CP 4 Titanium	Unalloyed titanium (ASTM F67) Grade 4, and	Unalloyed titanium (ASTM F67) Grade 4, and	CP 4 Titanium	Titanium Grade 4	Titanium 6AL-4V ELI

Characteristic	Proposed Device: (K250476)	Primary Predicate Device: (K090234)	Reference Device: (K202344)	Reference Device: (K232418)	Reference Device: (K222457)	Reference Device: (K223814)	Reference Device: (K023113)	Reference Device: (K080633)
				UTS ≥ 900MPa (cold-worked)	UTS ≥ 900MPa (cold-worked)			
Surface	Resorbable Blast Media, 2mm machined, grooved, anodized section only at coronal end	SBM (Soluble Blast Media) implant: HA blasted;	Anodic Oxidation	Grit-blasted, with a 3.0mm machined section only at coronal end	Grit-blasted, with a 3.0mm machined section only at coronal end	BioSpark™, AnaTite™ Blasted, hydrophilic surface enriched with calcium and phosphorous ions	TiUnite	SBM (Soluble Blast Media)
Surface Topography	Two level surface: Level 0 (collar): Sa (area roughness) <ul style="list-style-type: none"> Gold Maximum of 0.8µm Thickness (Thk) <ul style="list-style-type: none"> Gold $01.59,098 \mu\text{m} \pm .014\mu\text{m}$ Level 1 (body): Sa (area roughness) 1.5 µm -2.3 µm		TiUltra – Three level surface: <ul style="list-style-type: none"> Level 0 (collar): <ul style="list-style-type: none"> o Sa (area roughness) = 0.5 ± 0.3µm o Thickness (Thk) = 0.166±0.008µm Level 1 (transition): <ul style="list-style-type: none"> o Sa = 0.8 ± 0.3µm o Thk = 7.5±0.3µm Level 2 (body): <ul style="list-style-type: none"> o Sa = 1.5 ± 0.4µm o Thk = 12.0±1.2µm 	N/A	N/A	N/A	N/A	N/A