December 23, 2025

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

Re: K252145
Trade/Device Name: GEN5™ and GEN5+™ 3.3mmD Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: November 20, 2025
Received: November 24, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K252145

Device Name
GEN5™ and GEN5+™ 3.3mm Dental Implants

Indications for Use *(Describe)*
GEN5 and GEN5+ implants are two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially or fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework.
Implants can be indicated for immediate function when initial implant stability has been achieved and with appropriate occlusal loading.
• Short (<9mmL) Implants: Indicated for single tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.
• Narrow GEN5 Implants (3.3mmD), are indicated for single tooth replacement of mandibular central and lateral incisors, and maxillary lateral incisors, or splinted to other dental implants for multi-unit fixed or removable partial prostheses, or for denture stabilization.

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
GEN5™ and GEN5+™ 3.3mm Dental Implants
December 19, 2025

Manufacturer Name

Paragon Implant Mfg., LLC
27030 Malibu Hills Road
Calabasas, CA 91301, U.S.A.
Telephone (818) 475-4675

Official Contact

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Device Name and Classification

Trade/Proprietary Name	GEN5™ and GEN5+™ 3.3mm Dental Implants
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

Legally Marketed Predicate Device(s)

Primary Predicate Device (DZE - Implants)	K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts), Implant Direct Sybron Manufacturing, LLC
Reference Device (DZE - Implants)	K251938 (GEN5 and GEN5+ Dental Implant System), Paragon Implant Mfg., LLC
	K202344 (TiUltra Implants and Xeal Abutments), Nobel Biocare AB
	K241972 (BLUEDIAMOND IMPLANT), MegaGen Implant Co. Ltd

INDICATIONS FOR USE STATEMENT

GEN5 and GEN5+ implants are two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially or fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework.

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

- Short (<9mmL) Implants: Indicated for single tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.
- Narrow GEN5 Implants (3.3mmD), are indicated for single tooth replacement of mandibular central and lateral incisors, and maxillary lateral incisors, or splinted to other dental implants for multi-unit fixed or removable partial prostheses, or for denture stabilization.

SUBJECT DEVICE DESCRIPTION

The GEN5 and GEN5+ 3.3mmD Dental Implant System consists of root form Endosseous dental implants. The subject GEN5 and GEN5+ 3.3mm diameter implant bodies are bone-level.

GEN5 and GEN5+ Dental Implants are supplied as a two-piece implant assembly for use in a two-stage or 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 or as a free-standing single tooth replacement. The standard GEN5 Implants are for use in a two-stage surgical procedure. The first surgery is implant placement, and the second surgery is a few weeks prior to the start of prosthetic rehabilitation. By the addition of an abutment of any type at time of implant placement, the implant functions as a one-stage, two-piece system.

The GEN5 Implant and GEN5+ Implant are the exact same dental implant (internal hex implant). The difference between the two is that the GEN5+ Implant includes a pre-attached hex engaging Extender Healing Abutment (accessory restorative component) attached to the GEN5 Implant prior to packaging requiring only a single surgical procedure prior to prosthetic rehabilitation.

The top (coronal portion) of the GEN5 3.3mmD Implant body is with an endosseous 2.0mm straight neck. The lower apical aspect of the Implant is tapered with double-lead progressively deeper buttress threads. Three cutting flutes extend over the tapered portion of the implant's body. The GEN5+ Implants offer the additional flexibility of a 2mm extender collar that can serve as the trans-mucosal collar of an abutment or can be removed for abutment connection directly to the top of the implant for vertical flexibility.

The GEN5 and GEN5+ (3.3mmD) dental implant body is available in four lengths (9mm, 11mm, 12.5mm, and 14mm). GEN5 and GEN5+ Implants have 2.0mmL of their coronal surface anodized with a gold (3.5mmD) color for aesthetic purposes and to help identify the appropriate prosthetic components while the remainder of the Implant has gone through a surface treatment (blasting) to create a microtextured surface roughness. The anodization and blasting for the subject devices is identical to the anodization and blasting processes in the K251938 (GEN5 and GEN5+ Dental Implant System) clearance.

These Implants (and the devices included in the packaging) are sold sterile. The GEN5 and GEN5+ 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 GEN5 and GEN5+ (3.3mmD) have an internal hex for abutment connection, which is designed to receive multiple abutment variations expanding its restorative options and allowing for the implant to be used for support of attachment-retained overdentures and cement-retained or screw-retained prostheses.

The GEN5 Implants are provided with an Internal Hex Carrier while the GEN5+ Implants (a GEN5 Implant pre-fitted with an Extender Healing Abutment) are packaged with an Extender Carrier and an Extender Carrier Fixation Screw.

The devices are sold in gamma irradiated sterile packaging which consists of an outer vial and an inner vial which is sealed with a threaded cap.

The Extender Carriers and Extender Carrier Fixation 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).

The various devices included in the GEN5 and GEN5+ (3.3mmD) Dental Implant System (such as Endosseous dental implant abutments 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 complete dental restoration.

These various devices are not part of this submission but are cleared under K251938 (GEN5 and GEN5+ Dental Implant System). The prosthetic and restorative components (Straight Contoured, Angled-Contoured, ASC, Multi-Unit Abutments, Titanium Multi-Unit Abutment Copings, Titanium Temporary, Healing, Extenders, Cover Screws, Transfers, and Analogs) are all manufactured from titanium alloy (Ti-6Al-4V ELI) and anodized. The prosthetic components (PEEK Temporary Abutments) are all manufactured from polyetheretherketone (PEEK).

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence 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/.
- Fatigue (Dynamic Load) testing following ISO 14801 and Class II FDA Special Controls Guidance for worst-case dental implant system configurations containing angled abutments.
- Torsional yield, driving (insertion) torque, pullout load testing per ASTM F543 A1, A2, A3.
- Simulation and Physical MRI validations per ASTM F2052, ASTM F2119, ASTM F2182, and ASTM F2213.
- Accelerated aging per ASTM F1980-21 Because the packaging is a vial with a cap, determination of shelf-life by means of conventional package integrity testing after aging is not applicable. Therefore,

shelf-life of the sterile barrier was determined by membrane filtration sterility testing of the interior of the vial according to ISO 11737-2 after accelerated aging according to ASTM F1980.

- 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 are similar to those of the Nobel TiUltra implant body (K202344).
- 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>. No clinical data was included in this submission.
- 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 placement, before and after 3mm of resorption.
- Pullout load testing was conducted on short implants to evaluate indirect BIC using bone level placement.

EQUIVALENCE TO MARKETED DEVICES

The proposed GEN5 and GEN5+ (3.3mmD) Dental Implant System consists of root form Endosseous dental implants.

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 (K192221) are anodized and blasted with a soluble blast media to create a microtextured surface roughness below the bone level region of the Implant.

The proposed Implant diameters correspond to the various diameters offered by the predicate devices (K192221).

The proposed Implants have similar straight/tapered body shape as the predicate device (K192221). The top straight neck portion of the proposed device is different from the predicate device (K192221) in that the proposed device has horizontal grooves at 1mm, 2mm and 2.5mm from the top of the implant while the predicate device (K192221) does not.

The difference is the proposed device has a machined anodized collar which is identical in length and manufacturing process to the anodized collars cleared in K251938 (GEN5 and GEN5+ Dental Implant System).

The lower portion of the proposed and predicate device (K192221) both have buttress threads but differ in that the proposed device has double-lead threads while the predicate device (K192221) has triple-lead threads. The lower tapered portion of the proposed device has two cutting flutes while the predicate device (K192221) has three cutting grooves.

The body diameter of the proposed Implants are within the same range to those of the predicate device (K192221). The lengths of the proposed Implants are similar to those of the predicate device (K192221). GEN5 and GEN5+ 3.3mm Implants are within the same range offered at 9mm, 11mm, 12.5mm, and 14mm length diameters. The platforms of the proposed device are similar to the predicate device (K192221).

The additional devices provided inside the packaging differ from the proposed device and predicate device (K192221).

Both the proposed device and the predicate device (K192221) are packaged in a vial and cap with labels. The Implants, Healing Abutments, and Cover Screw of the proposed and predicate device(K192221) 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 (IMPLANTS) outlines the Intended Use and Technological Characteristics of each predicate and reference device

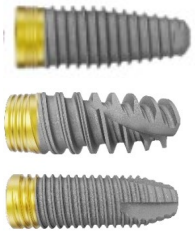
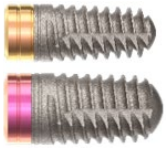
CONCLUSION

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 (IMPLANTS)

SUBSTANTIAL EQUIVALENCE COMPARISON IN TABULAR FORMAT

Design Parameter	Subject Device: (K252145) GEN5™ and GEN5+™(3.3mmD) Dental Implant System	Primary Predicate Device: (K192221) Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts, Implant Direct Sybron Manufacturing, LLC	Reference Device: (K202344) TiUltra Implants and Xeal Abutments Nobel Biocare AB	Reference Device: (K241972) BLUEDIAMOND IMPLANT, MegaGen Implant Co., Ltd.	Reference Device: (K251938) GEN5 and GEN5+ Dental Implant System, Paragon Implant Mfg., LLC
Regulation	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
Product code	DZE	DZE, NHA	DZE	DZE	DZE; NHA
Materials	Titanium 6AL-4V ELI	Titanium 6AL-4V ELI	Commercially pure titanium	CP Ti Grade 4	Titanium 6AL-4V ELI
Reason for Predicate/Reference	N/A	• Same General Design • Same Body Diameters • Same Connection Type • Same Sterilization • Same Material • Same/similar lengths, within 6mm–16mm size range of predicate • Same/similar Screw size GEN5 and GEN5+ do not offer M1.6 screw size • Same/similar Platform within size range of predicate • Difference(s): GEN5+ Implant: Supplied with pre-attached Implant Healing Abutment, Carrier and screw • Difference(s) Cutting Flutes Double Lead-Thread vs. Triple Lead-Thread • Difference(s) predicate has micro-thread, subject has machined anodized collar	Collar design, 2mm anodized machined endosseous collar with horizontal grooves	2.0 mm machined, unthreaded collar	• 2.0mm anodized machined, grooved, collar • Manufacturing (Anodizing, cleanliness) process
General Design	Threaded Root form implant	Threaded Root form implant	Threaded Root form implant	Threaded Root form implant	Threaded Root form implant
Implant Diameters	3.3mm	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	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	4.0mm, 4.4mm, 4.7mm, 4.8mm, 5.1mm	3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm
Implant Lengths	9mm, 11mm, 12.5mm, and 14mm	6mm (only simplyLegacy), 8mm, 10mm, 11.5mm, 13mm, 16mm	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	7.0mm, 8.0mm, 9.0mm, 10mm, 11mm, 13mm, 15mm	7mm, 9mm, 11mm, 12.5mm, and 14mm
Implant Platform	3.5mm	3.0mm, 3.5mm, 4.5mm, 5.7mm	Internal conical connection with hex interface	N/A	For 3.7mm, 4.2mm implants: 3.5mm For 4.7mm, 5.2mm, 5.7mm: 4.5mm
Cutting Flutes	Double (2)	3 (Legacy2/4); 2 (Legacy3)	N/A	N/A	Double (2)
Connection Type	Internal hex	Internal hex	Internal hex	Internal Octa	Internal hex
Screw Size	1-72 UNF 2A	M1.6 and 1-72 UNF 2A	N/A	N/A	1-72 UNF 2A
Implant Assembly	GEN5 Implant Supplied with friction-fit Carrier; GEN5+ Implant: Supplied with pre-attached Implant Healing Abutment, Carrier and screw.	Implant is assembled with one-piece (Legacy2, 3) or two-piece (Legacy4) fixture-mount. simplyLegacy2, 3: No carrier or fixture mount.	N/A	N/A	GEN5 Implant Supplied with friction-fit Carrier; GEN5+ Implant: Supplied with pre-attached Implant Healing Abutment, Carrier and screw.
Sterilization	Implants, Healing Abutments, and Cover Screws supplied sterile; Provided sterile	Supplied sterile; fixture-mounts sterilized by end user when used as abutments.	Provided sterile	Provided sterile	Implants, Healing Abutments, and Cover Screws supplied sterile; Provided sterile All other devices supplied non-sterile. Devices steam sterilized (when applicable) by end user as per Instructions for Use (IFU)
Surface	Resorbable Blast Media, 2.0mm machined, grooved, anodized section only at coronal end	SBM (Soluble Blast Media) implant: HA blasted; HA (Hydroxyapatite) implant: HA blasted/HA coated	Anodic oxidation	Sand-blasted, large grit, Acid-etched (S.L.A) Machined collar	Resorbable Blast Media, 2.0mm machined, grooved, anodized section only at coronal end
Surface Topography	Two level surface: Level 0 (collar): Sa (area roughness) • 0.6 µm ± 0.2 µm Thickness (Thk) • Gold 0.098 µm ± .014 µm Sa (area roughness) 1.5 µm -2.3 µm Thk	Level 1 (body): • Sa (area roughness) 1.5 µm -2.3 µm	TiUltra – Three level surface: • Level 0 (collar): o Sa (area roughness) = 0.5 ± 0.3µm o Thickness (Thk) = 0.166±0.008µm • Level 1 (transition): o Sa = 0.8 ± 0.3µm o Thk = 7.5±0.3µm • Level 2 (body): o Sa = 1.5 ± 0.4µm o Thk = 12.0±1.2µm	N/A	Two level surface: Level 0 (collar): Sa (area roughness) • 0.6µm ± .2 µm Thickness (Thk) • Gold 0.098 µm ± .014 µm • Rose Gold 0.110 µm ± .015 µm Level 1 (body): Sa (area roughness) 1.5 µm -2.3 µm Thk

Design Parameter	Subject Device: (K252145) GEN5™ and GEN5+™(3.3mmD) Dental Implant System	Primary Predicate Device: (K192221) Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts, Implant Direct Sybron Manufacturing, LLC	Reference Device: (K202344) TiUltra Implants and Xeal Abutments Nobel Biocare AB	Reference Device: (K241972) BLUEDIAMOND IMPLANT, MegaGen Implant Co., Ltd.	Reference Device: (K251938) GEN5 and GEN5+ Dental Implant System, Paragon Implant Mfg., LLC
Image					
Indications for Use	GEN5 and GEN5+ implants are two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially or fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate function when initial implant stability has been achieved and with appropriate occlusal loading. • Short (<9mmL) Implants: Indicated for single tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization. • Narrow GEN5 Implants (3.3mmD), are indicated for single tooth replacement of mandibular central and lateral incisors, and maxillary lateral incisors, or splinted to other dental implants for multi-unit fixed or removable partial prostheses, or for denture stabilization.	Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 dental implants are two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. *Narrow (3.2mmD) implants: Indicated for single-tooth replacement (mandibular central and lateral incisors; maxillary lateral incisors), multiple-tooth replacements or denture stabilization. *Short (<10mm) 3.7mm implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization. The Legacy 2, Legacy3, and Legacy4 fixture-mounts are intended for use with the corresponding dental implants (Legacy2, Legacy3, and Legacy4, respectively). The fixture-mounts can function as an abutment. As an abutment, fixture-mounts are intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients. *Fixture-mounts as an abutment for narrow (3.2mmD) implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. *Fixture-mounts as an abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors. Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 implants are compatible with the following abutments. Manufacturer: Implant Direct; Abutment Line: Legacy; Platform Diameter: 3.0mm, 3.5mm, 4.5mm, 5.7mm	NobelActive TiUltra implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelActive TiUltra implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive TiUltra 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. NobelActive TiUltra 3.0 implants are indicated for single-unit restorations only. NobelReplace CC TiUltra NobelReplace CC TiUltra implants are endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The NobelReplace CC TiUltra implants are indicated for single or multiple unit restorations. The NobelReplace CC TiUltra implants can be used in splinted or 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. 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	The BLUEDIAMOND IMPLANT is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: - Delayed loading - Immediate loading when good primary stability is achieved and with appropriate occlusal loading. For the BLUEDIAMOND IMPLANTS with a Thread Length of 5mm, It is indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks. It is specifically recommended for: - Fixed partial dentures/splinted units (one implant per unit) - Pontic cases in combination with at least one longer implant - Fully edentulous cases with at least one 5 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants.	GEN5 and GEN5 Implants: GEN5 and GEN5+ implants are two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially or fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate function when initial implant stability has been achieved and with appropriate occlusal loading. Short (<9mmL) Implants: Indicated for single tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization. GEN5 and GEN5+ Abutment System: The GEN5 and GEN5+ Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients, using traditional crown & bridge techniques

Design Parameter	Subject Device: (K252145) GEN5™ and GEN5+™(3.3mmD) Dental Implant System	Primary Predicate Device: (K192221) Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts, Implant Direct Sybron Manufacturing, LLC	Reference Device: (K202344) TiUltra Implants and Xeal Abutments Nobel Biocare AB	Reference Device: (K241972) BLUEDIAMOND IMPLANT, MegaGen Implant Co., Ltd.	Reference Device: (K251938) GEN5 and GEN5+ Dental Implant System, Paragon Implant Mfg., LLC
			appropriate stability has been achieved.		
Sterilization	Gamma irradiation	Gamma irradiation	Gamma Radiation (SAL 10^{-6})	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