



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

October 30, 2025

Re: K251938

Trade/Device Name: GEN5 and GEN5+ Dental Implant System  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: DZE, NHA  
Dated: September 26, 2025  
Received: September 29, 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](mailto: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

## Indications for Use

510(k) Number (*if known*)

K251938

Device Name

GEN5 and GEN5+ Dental Implant System

### Indications for Use (*Describe*)

**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.

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+ Dental Implant System**  
**October 29, 2025**

<b>Manufacturer Name</b>	Paragon Implant Mfg., LLC 27030 Malibu Hills Road Calabasas, CA 91301, U.S.A. Telephone (818) 475-4675
<b>Official Contact</b>	Renee Bennett, Manager of Regulatory Affairs Paragon Implant Mfg., LLC 27030 Malibu Hills Road Calabasas, CA 91301 Telephone: +1-818-475-4675 Email: rbennett@paragon-implant.com
<b>Device Name and Classification</b>	
Trade/Proprietary Name	GEN5™ and GEN5+™ 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; NHA
<b>Legally Marketed Predicate Device(s)</b>	
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)	K202344 (TiUltra Implants and Xeal Abutments), Nobel Biocare AB
Primary Predicate Device (NHA - Abutments)	K241972 (BLUEDIAMOND IMPLANT), MegaGen Implant Co., Ltd.
Reference Devices (NHA - Abutments)	K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts), Implant Direct Sybron Manufacturing, LLC
<b>K161655 (On1 Concept), Nobel Biocare AB</b>	

K052600 [Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled)], Zimmer Dental Inc.

K090234 (Spectra System Dental Implants 2008),  
Implant Direct LLC

K061319 (Spectra System), Implant Direct LLC

K060063 (Legacy Abutment System), Implant Direct LLC

K143011 (2014 InterActive/ SwishActive System),  
Implant Direct Sybron Manufacturing LLC

#### INDICATIONS FOR USE STATEMENT

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.

#### SUBJECT DEVICE DESCRIPTION

The GEN5™ and GEN5+ Dental Implant System consists of a root form Endosseous dental implant, Endosseous dental implant abutment, and various other prosthetic/restorative components (medical devices) to plan, implant, and support restorations for edentulous patients.

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 for implant placement, and the second surgery is a few weeks prior to 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) screw-retained on the GEN5 Implant prior to packaging requiring only a single surgical procedure prior to prosthetic rehabilitation.

The top (coronal portion) of the GEN5 Implant body is with a 2.0mm straight neck. The depth gauge lines at 1mm, 2mm and 2.5mm (or at 1mm and 2mm on the ≤9mm length) from the top of the implant facilitate the placement level with the crest of the ridge or 1mm above the crest of the ridge for all implants except the 3.7mmD x 7mmL. 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+ dental implant body is available in five diameter sizes (3.7mm, 4.2mm, 4.7mm, 5.2mm, and 5.7mm) with two platform diameters (3.5mm or 4.5mm), and five lengths (7mm, 9mm, 11mm, 12.5mm, and 14mm). GEN5 and GEN5+ Implants have 2.0mmL of their coronal surface anodized with either a gold (3.5mmD) or a rose gold (4.5mmD) color for aesthetic purposes to help identify the two platform diameters while the remainder of the Implant has gone through a surface treatment (blasting) to create a microtextured surface roughness. 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+ 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+ 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 a complete dental restoration.

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/.
- Cleaning and sterilization validations for all devices sold non-sterile per ISO 17664-1, AAMI TIR12, and ISO17665.
- 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>.
- 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 on short implants to evaluate indirect BIC using bone level placement.
- No clinical data was included in this submission.

## EQUIVALENCE TO MARKETED DEVICES

The proposed GEN5 and GEN5+ 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.

**K251938**  
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 conical connection of the proposed Implants has the identical angulation as the predicate device (K192221). The implant-abutment conical connection is identical to that of the predicate devices (K192221). 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, with the anodized portion being substantially equivalent to the reference device (K202344), dimensionally, in surface roughness, in surface area and surface thickness, and the machined collar of reference device (K241972) in length. The predicate device (K192221) has quadruple-lead micro-threads on the coronal aspect of the implant.

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 diameters of the proposed Implants are identical to those of the predicate device (K192221). The only exception is that GEN5 and GEN5+ Implants are not offered in the 3.2mm and 7.0mm body diameters. The lengths of the proposed Implants are similar to those of the predicate device (K192221). GEN5 and GEN5+ Implants are within the similar range offered at 7mm, 9mm, 11mm, 12.5mm, and 14mm length diameters. The platforms of the proposed device are similar to the predicate device (K192221). The only exception is that GEN5 and GEN5+ Implants are not offered in the 3.0mm and 5.7mm platform diameters.

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 the similar materials. The subject device and the reference devices encompass similar range of physical dimensions, are packaged in the 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)

Table 2. Substantial Equivalence (ABUTMENTS)

Design Parameter	Subject Device: K243960 GEN5™ and GEN5+™ 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.
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)
Classification	Class II	Class II	Class II	Class II
Product code	DZE	DZE	DZE	DZE
Materials	Titanium 6AL-4V ELI	Titanium 6AL-4V ELI	Commercially pure titanium	CP Ti Grade 4
Reason for Predicate/Reference	N/A	<ul style="list-style-type: none"> <li>• Same General Design</li> <li>• Same Body Diameters</li> <li>• Same Connection Type</li> <li>• Same Sterilization</li> <li>• Same Material</li> <li>• Same/similar lengths, within 6mm–16mm size range of predicate</li> <li>• Same/similar Screw size GEN5 and GEN5+ do not offer M1.6 screw size</li> <li>• Same/similar Platform within size range of predicate</li> <li>• Difference(s): GEN5+ Implant: Supplied with pre-attached Implant Healing Abutment, Carrier and screw</li> <li>• Difference(s) Cutting Flutes Double Lead-Thread vs. Triple Lead-Thread</li> <li>• Difference(s) predicate has micro-thread, subject has machined anodized collar</li> </ul>	<p>Collar design, 2mm anodized machined endosseous collar with horizontal grooves</p>	2.0 mm machined, unthreaded collar
General Design	Threaded Root form implant	Threaded Root form implant	Threaded Root form implant	Threaded Root form implant
Implant Diameters	3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm	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	Ø 4.0 Ø 4.4 Ø 4.7 Ø 4.8 Ø 5.1
Implant Lengths	7mm, 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
Implant Platform	For 3.7mm, 4.2mm implants: 3.5mm For 4.7mm, 5.2mm, 5.7mm: 4.5mm	3.0mm, 3.5mm, 4.5mm, 5.7mm	Internal conical connection with hex interface	N/A
Cutting Flutes	Double (2)	3 (Legacy2/4); 2 (Legacy3)	N/A	N/A
Connection Type	Internal hex	Internal hex	Internal hex	Internal Octa
Screw Size	1-72 UNF 2A	M1.6 and 1-72 UNF 2A	N/A	N/A
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
Sterilization	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)	Supplied sterile; fixture-mounts sterilized by end user when used as abutments.	Provided sterile	Provided sterile
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
Surface Topography	Two level surface: Level 0 (collar): Sa (area roughness) • $0.6\mu\text{m} \pm .2\mu\text{m}$ Thickness (Thk) • Gold $0.098\mu\text{m} \pm .014\mu\text{m}$ • Rose Gold $0.110\mu\text{m} \pm .015\mu\text{m}$ Level 1 (body): Sa (area roughness) $1.5\mu\text{m} - 2.3\mu\text{m}$ Thk	Level 1 (body): • Sa (area roughness) $1.5\mu\text{m} - 2.3\mu\text{m}$	TiUltra – Three level surface: • Level 0 (collar): o Sa (area roughness) = $0.5 \pm 0.3\mu\text{m}$ o Thickness (Thk) = $0.166 \pm 0.008\mu\text{m}$ • Level 1 (transition): o Sa = $0.8 \pm 0.3\mu\text{m}$ o Thk = $7.5 \pm 0.3\mu\text{m}$ • Level 2 (body): o Sa = $1.5 \pm 0.4\mu\text{m}$ o Thk = $12.0 \pm 1.2\mu\text{m}$	N/A
Image	 	 		

Design Parameter	Subject Device: K243960 GEN5™ and GEN5+™ 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.
Indications for Use	<p><b>Indications for Use:</b></p> <p>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.</p> <p>Implants can be indicated for immediate function when initial implant stability has been achieved and with appropriate occlusal loading.</p> <p>Short (&lt;9mmL) Implants: Indicated for single tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.</p> <p>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 &amp; bridge techniques.</p>	<p><b>Indications for Use:</b></p> <p>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.</p> <p>Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.</p> <p>*Narrow (3.2mmD) implants: Indicated for single-tooth replacement (mandibular central and lateral incisors; maxillary lateral incisors), multiple-tooth replacements or denture stabilization.</p> <p>*Short (&lt;10mm) 3.7mm implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.</p> <p>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.</p> <p>*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.</p> <p>*Fixture-mounts as an abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.</p> <p>Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 implants are compatible with the following abutments.</p> <p>Manufacturer: Implant Direct; Abutment Line: Legacy; Platform Diameter: 3.0mm, 3.5mm, 4.5mm, 5.7mm</p>	<p><b>Indications for Use:</b></p> <p>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.</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. 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.</p> <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 &lt;7mm length are for delayed loading only when appropriate stability has been achieved.</p>	<p>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.</p> <p>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.</p>
Sterilization	Gamma irradiation	Gamma irradiation	Gamma Radiation (SAL 10-6 )	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

**Table 2. Substantial Equivalence (ABUTMENTS)**

## Predicates: Legacy™ System Abutment Types:

## Predicates for GEN5+ Extender: Nobel On1™ Base (K161655)

**Table 2. Substantial Equivalence (Extender Healing Abutment)**

Table 2. Substantial Equivalence (Extender Healing Abutment)											
	Straight Contoured Abutment	Angled Abutment	Titanium Temporary Abutment	Plastic (PEEK) Temporary Abutment	Angled Screw Channel (ASC) Abutments (Engaging)	Angled Screw Channel (ASC) Abutments (Non-Engaging)	Straight Multi-Unit Abutments (MUA)	Angled Multi-Unit Screw-Receiving Abutment	Extender Healing Abutment	Healing Abutment	Cover Screw
Device Image	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		N/A	N/A
Connection	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Internal Conical Connection	N/A	N/A
Supplied Sterile	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Sterile	N/A	N/A

**Predicates for GEN5+ Extender: Hex-Lock Prepared Abutment (Straight & Angled) - [Tapered Screw Vent (TSV) Abutments (friction fit)]: (K052600)**

**Table 2. Substantial Equivalence (Extender Healing Abutment)**

## Technological Characteristics Comparison Table – Abutment Designs

Comparison	Subject Device K243960 (GEN5 and GEN5+ Dental Implant System)	Predicate Device K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	Reference Device K161655 (On1 Concept) Nobel Biocare AB	Reference Device K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	Reference Device K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	Reference Device K061319 (Spectra System) Implant Direct LLC	Reference Device K060063 (Legacy Abutment System) Implant Direct LLC	Reference Device K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC	
Product Code	NHA	NHA	NHA	NHA	NHA	NHA	NHA	NHA	
Regulation	21 C.F.R. §872.3640, 21 C.F.R. §872.3630	21 C.F.R. §872.3640, 21 C.F.R. §872.3630	21 C.F.R. §872.3630	21 C.F.R. §872.3630	21 C.F.R. §872.3640, 21 C.F.R. §872.3630	21 C.F.R. §872.3640	21 C.F.R. §872.3630	21 C.F.R. §872.3640, 21 C.F.R. §872.3630	
Classification	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Class II	
Reason for Predicate / Reference	Not Applicable	<u>Legacy Extender</u> <u>Healing Abutments</u> <ul style="list-style-type: none"> <li>• Same General Design</li> <li>• Same Intended Use</li> <li>• Same Diameters</li> <li>• Same Connection Type</li> <li>• Same Sterilization</li> <li>• Same Usage</li> <li>• Same Material</li> <li>• Same/similar Screw size - GEN5 and GEN5+ do not offer M1.6 screw size</li> <li>• Same Platform size</li> <li>• Same Collar height</li> <li>• Same Post height</li> <li>• Different finish: The predicate is not anodized.</li> </ul>	<u>On1 Base</u> <u>(Extender)</u> <ul style="list-style-type: none"> <li>• Same General Design</li> <li>• Same Intended Use</li> <li>• Same Usage</li> <li>• Same Material</li> <li>• Same/Similar Platform sizes</li> <li>• Similar Collar height</li> <li>• Both are anodized.</li> </ul>	<u>Hex-Lock Abutments</u> <u>(Straight and Angled)</u> <ul style="list-style-type: none"> <li>• Same General Design</li> <li>• Same Intended Use</li> <li>• Same/Similar Diameters</li> <li>• Same connection Type</li> <li>• Same Usage</li> <li>• Same Material</li> <li>• Same screw size</li> <li>• Same Platform size</li> </ul>	<ul style="list-style-type: none"> <li>• Same General Design</li> <li>• Same Intended Use</li> <li>• Same Sterilization</li> <li>• Same Usage</li> <li>• Same Material</li> <li>• Same Connection</li> <li>• Same Connection</li> <li>• Same Angle</li> <li>• Same/similar Screw size - GEN5 and GEN5+ do not offer M1.6 screw size</li> </ul>	<ul style="list-style-type: none"> <li>• Same General Design</li> <li>• Same Intended Use</li> <li>• Same Sterilization</li> <li>• Same Usage</li> <li>• Same Material</li> <li>• Same Connection</li> <li>• Same Angle</li> </ul>	<u>Legacy Straight</u> <u>Contoured</u> <u>Abutments</u> <ul style="list-style-type: none"> <li>• Same/Similar Diameters;</li> <li>Predicate offers an additional diameter.</li> </ul>	<u>Legacy Temporary</u> <u>Abutments</u> <ul style="list-style-type: none"> <li>• Same General Design</li> <li>• Same Intended Use</li> <li>• Same Diameters</li> <li>• Same Connection Type</li> <li>• Same Sterilization</li> <li>• Same Usage</li> <li>• Same Material</li> <li>• Same Angle</li> <li>• Same/similar Screw size - GEN5 and GEN5+ do not offer M1.6 screw size</li> <li>• Same Platform size</li> <li>• Same Collar height</li> <li>• Different Post height; Subject approx. 9.7mm; Predicate approx. 9.0mm</li> <li>• Same Width: Subject approx.</li> </ul>	<u>Legacy Angled Multi-Unit</u> <u>Screw-Receiving Abutments</u> <ul style="list-style-type: none"> <li>• Same General Design</li> <li>• Same Intended Use</li> <li>• Same Diameters</li> <li>• Same Connection Type</li> <li>• Same Sterilization</li> <li>• Same Usage</li> <li>• Same Material</li> <li>• Same Angle</li> <li>• Same/similar Screw size - GEN5 and GEN5+ do not offer M1.6 screw size</li> <li>• Same Platform size</li> <li>• Same Collar height</li> <li>• Different Post height; Subject approx. 9.7mm; Predicate approx. 9.0mm</li> <li>• Same Width: Subject approx.</li> </ul>

Comparison	<b>Subject Device</b> K243960 (GEN5 and GEN5+ Dental Implant System)	<b>Predicate Device</b> K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	<b>Reference Device</b> K161655 (On1 Concept) Nobel Biocare AB	<b>Reference Device</b> K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	<b>Reference Device</b> K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	<b>Reference Device</b> K061319 (Spectra System) Implant Direct LLC	<b>Reference Device</b> K060063 (Legacy Abutment System) Implant Direct LLC	<b>Reference Device</b> K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
					<ul style="list-style-type: none"> <li>Different finish: The predicate is not anodized.</li> </ul> <p><u>Legacy Healing Abutments</u></p> <ul style="list-style-type: none"> <li>Same Platform sizes; Predicate offers additional sizes.</li> <li>Same Collar height; Predicate offers additional size.</li> <li>Same/Similar Lengths; Predicate offers additional lengths.</li> <li>Similar Widths: Subject range: 3.7mm – 5.7mm; Predicate 3.8mm – 6.6mm</li> <li>Same finish</li> </ul> <p><u>Legacy Straight Contoured Abutments</u></p> <ul style="list-style-type: none"> <li>Same Diameters; Predicate offers additional diameter.</li> <li>Same Platform sizes and additional platform size is within the predicate additional size</li> </ul>	<p>2.4mm; predicate approx. 2.7mm</p> <ul style="list-style-type: none"> <li>Same Collar height</li> <li>Same Post height</li> <li>Same Finish</li> </ul> <p><u>Legacy Angled Abutments</u></p> <ul style="list-style-type: none"> <li>Same Diameters; Predicate offers additional diameter.</li> <li>Same Platform sizes; Predicate offers an additional platform size.</li> <li>Same Collar height</li> <li>Same Post height</li> <li>Same Finish</li> </ul> <p><u>Legacy Straight Multi-Unit Abutment (MUA)</u></p> <ul style="list-style-type: none"> <li>Same Diameters</li> <li>Same Platform sizes; Predicate offers an additional platform size.</li> <li>Same/Difference Lengths: Both offer 1mm, 2mm, 4mm; subject also offers 3mm and 5mm.</li> <li>Different Finish: Subject anodizes; predicate none.</li> </ul>		

Comparison	<b>Subject Device</b> K243960 (GEN5 and GEN5+ Dental Implant System)	<b>Predicate Device</b> K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	<b>Reference Device</b> K161655 (On1 Concept) Nobel Biocare AB	<b>Reference Device</b> K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	<b>Reference Device</b> K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	<b>Reference Device</b> K061319 (Spectra System) Implant Direct LLC	<b>Reference Device</b> K060063 (Legacy Abutment System) Implant Direct LLC	<b>Reference Device</b> K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
					range 3.0mm – 5.7mm. <ul style="list-style-type: none"> <li>• Same Collar height</li> <li>• Same Post height</li> <li>• Same Finish</li> </ul> <u>Legacy Angled Abutments</u> <ul style="list-style-type: none"> <li>• Same Diameters; Predicate offers additional diameter.</li> <li>• Same Platform sizes; Predicate offers an additional platform size.</li> <li>• Same Collar height</li> <li>• Same Post height</li> <li>• Same Finish</li> </ul> <u>Legacy Straight Multi-Unit Abutment (MUA)</u> <ul style="list-style-type: none"> <li>• Same Diameters</li> <li>• Same Platform sizes; Predicate offers an additional platform size.</li> <li>• Same/Difference Lengths: Both offer 1mm, 2mm, 4mm; subject also offers 3mm and 5mm.</li> </ul>	<u>Legacy Angled Multi-Unit Screw-Receiving Abutments</u> <ul style="list-style-type: none"> <li>• Same General Design</li> <li>• Same Diameters</li> <li>• Same Connection Type</li> <li>• Same Sterilization</li> <li>• Same Usage</li> <li>• Same Material</li> <li>• Same Angle</li> <li>• Same Screw size</li> <li>• Same Platform size</li> <li>• Same/Similar Collar Height: Both have 2mm; Subject has 1mm; Predicate has additional sizes offered.</li> <li>• Same Post height</li> <li>• Different finish: The predicate is not anodized.</li> </ul>		

Comparison	<b>Subject Device</b> K243960 (GEN5 and GEN5+ Dental Implant System)	<b>Predicate Device</b> K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	<b>Reference Device</b> K161655 (On1 Concept) Nobel Biocare AB	<b>Reference Device</b> K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	<b>Reference Device</b> K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	<b>Reference Device</b> K061319 (Spectra System) Implant Direct LLC	<b>Reference Device</b> K060063 (Legacy Abutment System) Implant Direct LLC	<b>Reference Device</b> K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC	
					<ul style="list-style-type: none"> <li>Different Finish: Subject anodizes; predicate none.</li> </ul> <p><u>Legacy Temporary Abutments</u></p> <ul style="list-style-type: none"> <li>Same/Similar Diameters; Predicate offers additional sizes.</li> <li>Same Platform sizes; Subject offers additional 4.7mm</li> <li>Same Collar height</li> <li>Different Post height: Subject Approx 9.7mm; Predicate approx. 9.0mm.</li> <li>Same finish</li> </ul> <p><u>Legacy PEEK Abutments</u></p> <ul style="list-style-type: none"> <li>Same Diameters; Predicate offers additional sizes.</li> <li>Same Platform size; Predicate offers additional sizes.</li> <li>Same Collar height</li> <li>Different Post height; Subject approx. 8mm; Predicate approx. 10.1mm.</li> </ul>				

Comparison	Subject Device K243960 (GEN5 and GEN5+ Dental Implant System)	Predicate Device K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	Reference Device K161655 (On1 Concept) Nobel Biocare AB	Reference Device K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	Reference Device K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	Reference Device K061319 (Spectra System) Implant Direct LLC	Reference Device K060063 (Legacy Abutment System) Implant Direct LLC	Reference Device K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
					• Same finish: None			
Prosthesis Attachment	Screw – or cement-retained	Screw – or cement-retained	Screw – or cement- retained	Screw – or cement-retained	Screw – or cement-retained	Screw – or cement-retained	Screw – or cement-retained	Screw – or cement-retained
Restoration	Single or multi- unit	Single or multi-unit	Single or multi- unit	Single or multi-unit	Single or multi- unit	Single or multi-unit	Single or multi-unit	Single or multi-unit
Sterilization Method – Sterile Devices (Implants, Healing Abutments, and Cover Screws)	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	Gamma Sterilization	N/A	Gamma Sterilization
Sterilization Method – Non- sterile Devices (All Other Devices)	Steam Sterilization by end user prior to use per IFU	Steam Sterilization by end user prior to use per IFU	Packaged as Sterile	Packaged as Sterile; Steam Sterilization by end user prior to use per IFU	Steam Sterilization by end user prior to use per IFU	Steam Sterilization by end user prior to use per IFU	Steam Sterilization by end user prior to use per IFU	Steam Sterilization by end user prior to use per IFU
Usage	Single use	Single use	Single Use	Single Use	Single use	Single use	Single use	Single use
Abutment Material	Ti-6Al-4V ELI alloy; PEEK	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy; PEEK	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy
Screw Size	1-72 UNF 2A and M1.6	1-72 UNF 2A and M1.6	M1.6 and M1.4	1-72 UNF 2A	1-72 UNF 2A and M1.6	1-72 UNF 2A	1-72 UNF 2A and M1.6	1-72 UNF 2A and M1.6
Abutment Screw Material	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy	Ti-6Al-4V ELI alloy
Use with Implant Diameters	3.7mm; 4.2mm; 4.7mm; 5.2mm; 5.7mm	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	3.5mm, 3.75, 4.3mm, 5.0mm, 5.5mm	3.7mm, 4.1mm, 4.7mm, 6.0mm	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	3.0mm, 3.2mm, 3.7mm, 4.2mm, 4.3mm, 4.7mm, 5.0mm, 5.2mm, 5.7mm, 7.0mm	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	3.2mm, 3.7mm, 5.0mm
Cover Screws	Platform Diameter:	N/A	N/A	N/A	Platform Diameter:	N/A	N/A	N/A

Comparison	Subject Device K243960 (GEN5 and GEN5+ Dental Implant System)	Predicate Device K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	Reference Device K161655 (On1 Concept) Nobel Biocare AB	Reference Device K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	Reference Device K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	Reference Device K061319 (Spectra System) Implant Direct LLC	Reference Device K060063 (Legacy Abutment System) Implant Direct LLC	Reference Device K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
	3.5mm and 4.5mm  Width: 3.4mm 4.4mm, 5.8mm  Length: 1.0mm, 2.0mm, 3.0mm  Finish: Anodized				3.0mm, 3.5mm, 4.5mm, 5.7mm  Width: 3.5mm, 4.5mm, 5.7mm  Finish: None			
Healing Abutments	Platform: 3.5mm, 4.5mm  Collar Height: 3mm, 5mm  Angle: Straight  Width: 3.7mm, 4.7mm, 5.7mm  Length: 3.0mm, 5.0mm  Angle: Straight  Finish:	N/A	N/A	N/A	Platform: 3.0mm, 3.5mm, 4.5mm, 5.7mm  Collar Height: 3mm, 5mm  Angle: Straight  Width: 3.8mmD, 4.8mm, 5.8mm, 6.6mm  Length: 3.0mm, 5.0mm, 7.0mm  Angle: Straight	N/A	N/A	N/A

Comparison	Subject Device K243960 (GEN5 and GEN5+ Dental Implant System)	Predicate Device K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	Reference Device K161655 (On1 Concept) Nobel Biocare AB	Reference Device K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	Reference Device K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	Reference Device K061319 (Spectra System) Implant Direct LLC	Reference Device K060063 (Legacy Abutment System) Implant Direct LLC	Reference Device K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
	Anodized				Finish: Anodized			
Extender Healing Abutments	Platform: 3.5mm, 4.5mm, 5.7mm  Collar Height: 1mm, 2mm  Post Height: Approx. 7.6mm  Interface Length: 2.0mm  Finish: Anodized	Platform: 3.5mm, 4.5mm, 5.7mm  Collar Height: 1mm, 2mm  Post Height: Approx. 7.6mm  Finish: None	Platform: 3.5mm (NP), 4.3mm (RP), 5.0mm (WP)  Collar Height: 1.75mm, 2.5mm  Finish: Anodized	Friction-Fit	N/A	N/A	N/A	N/A
Straight Contoured Abutments	Platform: 3.5mm, 4.5mm, 4.7mm, 5.7mm  Diameter: 3.7mm, 4.7mm, 5.7mm  Collar Height: 1mm, 2mm  Post Height: Approx, 7.6mm  Angle:	N/A	N/A	N/A	Platform: 3.0mm, 3.5mm, 4.5mm, 5.7mm  Diameter: 3.7mm, 4.7mm, 5.7mm, 6.5mm  Collar Height: 1mm, 2mm  Post Height: Approx. 7.6mm  Angle:	Platform: 3.5mm, 4.5mm, 5.0mm, 6.0mm  Diameter: 3.7mm, 4.7mm, 5.7mm, 6.5mm  Collar Height: 1mm, 2mm  Post Height: Approx. 7.6mm  Angle:	N/A	N/A

Comparison	Subject Device K243960 (GEN5 and GEN5+ Dental Implant System)	Predicate Device K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	Reference Device K161655 (On1 Concept) Nobel Biocare AB	Reference Device K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	Reference Device K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	Reference Device K061319 (Spectra System) Implant Direct LLC	Reference Device K060063 (Legacy Abutment System) Implant Direct LLC	Reference Device K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC	
	Straight  Hex Width: Approx 2.4mm  Interface Length: Approx 1.9mm  Finish: Anodized				Straight  Hex Width: Approx 2.7mm  Interface Length: Approx 1.9mm  Finish: Anodized	Straight  Hex Width: Approx 2.7mm  Interface Length: Approx 1.9mm  Finish: Anodized			
Angled Abutments	Platform: 3.5mm, 4.5mm, 4.7mm  Diameter: 4.7mm, 5.7mm  Collar Height: Approx. 0.75mm, 2mm  Post Height: Min. 7.75mm  Hex Width: Approx 2.4mm  Interface Length: Approx 1.9mm  Angle:	N/A	N/A	N/A	Platform: 3.0mm, 3.5mm, 4.5mm, 5.7mm  Diameter: 4.7mm, 5.7mm, 6.5mm  Collar Height: 0.75mm, 2mm  Post Height: Min. 7.75mm  Hex Width: Approx 2.7mm  Interface Length: Approx 1.9mm  Angle:	Platform: 3.0mm, 3.5mm, 4.5mm, 5.7mm  Diameter: 4.7mm, 5.7mm, 6.5mm  Collar Height: 0.75mm, 2mm  Post Height: Min. 7.75mm  Hex Width: Approx 2.7mm  Interface Length: Approx 1.9mm  Angle:	N/A	N/A	

Comparison	Subject Device K243960 (GEN5 and GEN5+ Dental Implant System)	Predicate Device K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	Reference Device K161655 (On1 Concept) Nobel Biocare AB	Reference Device K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	Reference Device K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	Reference Device K061319 (Spectra System) Implant Direct LLC	Reference Device K060063 (Legacy Abutment System) Implant Direct LLC	Reference Device K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
	Angled 15 degree  Finish: Anodized				Angled 15 degree  Finish: None	Angled 15 degree  Finish: None		
Angled Screw Channel (ASC) Engaging Abutments	Platform: 3.5mm, 4.5mm, 4.7mm  Diameter: 3.7mm, 4.7mm, 5.2mm, 5.7mm  Collar Height: 0.5mm, 2.0mm  Post Height: 4.75mm  Hex Width: Approx. 2.4mm  Interface Length: Approx. 1.9mm  Angle: Straight  Finish: Anodized	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Angled Screw Channel (ASC)	Platform:	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Subject Device K243960 (GEN5 and GEN5+ Dental Implant System)	Predicate Device K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	Reference Device K161655 (On1 Concept) Nobel Biocare AB	Reference Device K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	Reference Device K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	Reference Device K061319 (Spectra System) Implant Direct LLC	Reference Device K060063 (Legacy Abutment System) Implant Direct LLC	Reference Device K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
Non-Engaging Abutments	3.5mm, 4.5mm, 4.7mm  Diameter: 3.7mm, 4.7mm, 5.2mm, 5.7mm  Collar Height: 0.5mm, 2mm  Post Height: 4.75mm  Angle: Straight  Width: 3.7mm, 4.7mm  Finish: Anodized							
Straight Multi- Unit Abutment (MUA)	Platform: 3.5mm, 4.5mm, 4.8mm  Diameter: 4.8mm  Collar Height:	N/A	N/A	N/A	Platform: 3.0mm, 3.5mm  Diameter: 4.8mm  Collar Height: 1mm, 2mm, 4mm  Angle:	Platform: 4.5mm, 5.7mm  Diameter: 4.8mm  Collar Height: 1mm, 2mm, 4mm  Angle:	N/A	N/A

Comparison	Subject Device K243960 (GEN5 and GEN5+ Dental Implant System)	Predicate Device K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	Reference Device K161655 (On1 Concept) Nobel Biocare AB	Reference Device K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	Reference Device K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	Reference Device K061319 (Spectra System) Implant Direct LLC	Reference Device K060063 (Legacy Abutment System) Implant Direct LLC	Reference Device K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
	1.0mm, 2.0mm, 3.0mm, 4.0mm, 5.0mm  Angle: Straight  Finish: Anodized				Straight  Finish: None	Straight  Finish: None		
Angled Multi- Unit Screw- Receiving Abutments	Platform: 3.5mm, 4.5mm, 4.8mm  Diameter: 4.8mm, 5.5mm, 7.0mm  Collar Height: 1mm, 2mm  Post Height: Approx 2mm  Hex Width: Approx. 2.4mm  Interface Length: Approx 1.9mm  Angle:	N/A	N/A	N/A	N/A  Platform: 3.5mm, 4.5mm  Diameter: Approx 4.8mm  Collar Height: 2.0mm, 3.0mm, 4.0mm  Post Height: Approx 2mm  Hex Width: Approx. 2.7mm  Interface Length: Approx 1.9mm  Angle: 15 degrees; 30 degrees  Finish:	N/A  Platform: 3.5mm, 4.5mm  Diameter: Approx 4.8mm  Collar Height: 2.0mm, 3.0, 2.5mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm  Post Height: Approx 2mm  Hex Width: Approx. 2.7mm  Interface Length: Approx 1.9mm  Angle: 15 degrees; 30 degrees	N/A  Platform: 3.5mm, 4.5mm  Diameter: Approx 4.8mm  Collar Height: 2.0mm, 3.0, 2.5mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm  Post Height: Approx 2mm  Hex Width: Approx. 2.7mm  Interface Length: Approx 1.9mm  Angle: 15 degrees; 30 degrees	

Comparison	Subject Device K243960 (GEN5 and GEN5+ Dental Implant System)	Predicate Device K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	Reference Device K161655 (On1 Concept) Nobel Biocare AB	Reference Device K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	Reference Device K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	Reference Device K061319 (Spectra System) Implant Direct LLC	Reference Device K060063 (Legacy Abutment System) Implant Direct LLC	Reference Device K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
	17 degrees; 30 degrees  Finish: Anodized					None		Finish: None
Temporary Abutments	Platform: 3.5mm, 4.5mm, 4.7mm  Diameter: 4.7mm, 5.2mm, 5.7mm  Collar Height: Approx. 1mm  Post Height: Approx. 9.7mm  Angle: Straight  Finish: Anodized	N/A	N/A	N/A	Platform: 3.0mm, 3.5mm, 4.5mm, 5.7mm  Diameter: 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm; 6.5mm  Collar Height: Approx. 1mm  Post Height: Approx, 9.0mm  Angle: Straight  Finish: None	N/A	Platform: 3.5mm, 4.5mm  Diameter: 3.5mm, 5.7mm, 6.5mm  Collar Height: Approx. 1mm  Post Height: Approx, 9.0mm  Angle: Straight  Finish: Anodized	N/A
Plastic (PEEK) Temporary Abutments	Platform: 3.5mm, 4.5mm  Diameter:	N/A	N/A	N/A	Platform: 3.5mm, 4.5mm, 5.7mm  Diameter:	N/A	N/A	N/A

Comparison	<b>Subject Device</b> K243960 (GEN5 and GEN5+ Dental Implant System)	<b>Predicate Device</b> K192221 (Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts) Implant Direct Sybron Manufacturing, LLC	<b>Reference Device</b> K161655 (On1 Concept) Nobel Biocare AB	<b>Reference Device</b> K052600 (Zimmer Dental Hex-Lock Prepared Abutment (Straight & Angled) Zimmer Dental Inc.	<b>Reference Device</b> K090234 (Spectra System Dental Implants 2008) Implant Direct LLC	<b>Reference Device</b> K061319 (Spectra System) Implant Direct LLC	<b>Reference Device</b> K060063 (Legacy Abutment System) Implant Direct LLC	<b>Reference Device</b> K143011 (2014 InterActive/ SwishActive System) Implant Direct Sybron Manufacturing LLC
	4.7mm, 5.2mm, 5.7mm  Collar Height: 1.0mm  Post Height: Approx 8mm  Angle: Straight  Hex Width: Approx 2.4mm  Interface Length: Approx 1.9mm				3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm; 6.5mm  Collar Height: 1.0mm  Post Height: Approx 10.1mm  Angle: Straight:  Hex Width: Approx 2.7mm  Interface Length: Approx 1.9mm			