July 28, 2025

Infinitum Eta Ltd.
Avital Barlev
VP QA&RA
Hatnufa 6
Petach Tikva, 4951024
ISRAEL

Re: K251220
Trade/Device Name: NUVENTUS NV.C™ Prosthetic Components
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 20, 2025
Received: June 26, 2025

Dear Avital Barlev:

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)*
K251220

Device Name
NUVENTUS NV.C Prosthetic Components

Indications for Use *(Describe)*

NUVENTUS NV.C™ HEALING COMPONENTS

NUVENTUS NV.C™ healing components are indicated to be placed in fully or partially edentulous patients after implant placement. The healing components protect the inner configuration of the implant and form, maintain, and stabilize the soft tissue during the healing process. Healing components have a maximum duration of usage of 180 days.

NUVENTUS NV.C™ TEMPORARY PROSTHETIC COMPONENTS

NUVENTUS NV.C™ temporary prosthetic components are indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must not be placed in occlusion. Temporary prosthetic components have a maximum duration of usage of 180 days.

NUVENTUS NV.C™ MULTI-UNIT ABUTMENTS

NUVENTUS NV.C™ Multi-unit Abutments are indicated to be placed into NUVENTUS NV.C™ dental implants to provide a support structure for the functional and esthetic oral rehabilitation of fully or partially edentulous patients with bridges or full-arch prostheses.

NUVENTUS NV.C™ FINAL PROSTHETIC

NUVENTUS NV.C™ Multi-unit Final Coping is connected to the endosseous dental implant via multi-unit abutment and are indicated for use as an aid in prosthetic rehabilitations in fully or partially edentulous patients with bridges or full-arch prostheses.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY K251220
NUVENTUS NV.C™ Prosthetic Components
Infinitum Eta Ltd.

I. ADMINISTRATIVE INFORMATION

Manufacturer:	Infinitum Eta Ltd HaTnufa St 6 Petah Tikva, 4951024, Israel
Official contact :	Avital Barlev, Vice President QA&RA Telephone: +972-54-2272773 E-mail: avitalb@infinetamed,com
Date of Submission	July 23nd, 2025

II. DEVICE

Trade/ Device Name	NUVENTUS NV.C™ Prosthetic Components
Common Name	Dental Abutments
Classification Name	Endosseous Dental Implant Abutments
Regulation Number	21 CFR 872.3630
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental and ENT Devices)

III. PREDICATE DEVICE INFORMATION

PRIMARY PREDICATE DEVICE

- K071370; Nobel Biocare AB, Healing abutment conical connection NP, RP; Cover screw conical connection NP, RP, Temporary abutments and copings

- K220751; Institut Straumann AG, Straumann® BLX Temporary Ti Abutment

- K132746; Nobel Biocare AB, Clinical Screw CC NP/RP

- K161416; Nobel Biocare AB, Multi Unit Abutment Plus

- K113410; Institut Straumann AG, Straumann® Multi-base abutment coping Ti

IV. SUBJECT DEVICE DESCRIPTION

The NUVENTUS NV.C™ Prosthetic Components product portfolio consists of NUVENTUS NV.C™ Healing Components, NUVENTUS NV.C™ Temporary Prosthetic Components, NUVENTUS NV.C™ Multi-unit Abutments, and NUVENTUS NV.C™ Final Prosthetic. NUVENTUS NV.C™ Prosthetic Components product portfolio are intended to be used with the NUVENTUS NV.C™ Dental Implant System (K233081).

NUVENTUS NV.C™ HEALING COMPONENTS
NUVENTUS NV.C™ Healing Components may come in different designs, either with cap or screw portion machined as one piece or with an integrated occlusal screw. Different shapes, transmucosal heights are available.
Healing components are components that cover the implant or abutment platform and prevent tissue overgrowth during the healing phase of the implant. The threaded portion of the healing components fits inside the internal threads of the implant or abutment, while the head of the healing components covers the top surface of the implant (the implant head) or abutment.

NUVENTUS NV.C™ TEMPORARY PROSTHETIC COMPONENTS
The NUVENTUS NV.C™ Temporary Prosthetic Components line consists of abutments and copings which are used for the restoration of NUVENTUS NV.C™ Dental Implants of different types, endosteal diameters, lengths and platforms. They are available in a variety of shapes and sizes to fit individual patient needs.

NUVENTUS NV.C™ MULTI-UNIT ABUTMENTS
NUVENTUS NV.C™ Multi-unit Abutments are premanufactured dental abutments used for restoration of NUVENTUS NV.C™ Dental Implant of different diameters and lengths. The Multi-unit Abutments are available in NP and RP platform sizes; 0^0, 17^0 and 30^0 angulations; various transmucosal heights and hexagonal index orientations. Multi-unit Abutments are co-packed with abutment carrier and screw. The abutments are delivered sterile for immediate use.

NUVENTUS NV.C™ FINAL PROSTHETIC
The NUVENTUS NV.C™ Final Prosthetic line consists of abutments and copings which are used for the restoration of NUVENTUS NV.C™ Dental Implants of different types, endosteal diameters, lengths and platforms. They are available in a variety of shapes and sizes to fit individual patient needs.

V. INDICATION FOR USE

NUVENTUS NV.C™ HEALING COMPONENTS

NUVENTUS NV.C™ healing components are indicated to be placed in fully or partially edentulous patients after implant placement. The healing components protect the inner configuration of the implant and form, maintain, and stabilize the soft tissue during the healing process. Healing components have a maximum duration of usage of 180 days.

NUVENTUS NV.C™ TEMPORARY PROSTHETIC COMPONENTS

NUVENTUS NV.C™ temporary prosthetic components are indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must

not be placed in occlusion. Temporary prosthetic components have a maximum duration of usage of 180 days.

NUVENTUS NV.C™ MULTI-UNIT ABUTMENTS

NUVENTUS NV.C™ Multi-unit Abutments are indicated to be placed into NUVENTUS NV.C™ dental implants to provide a support structure for the functional and esthetic oral rehabilitation of fully or partially edentulous patients with bridges or full-arch prostheses.

NUVENTUS NV.C™ FINAL PROSTHETIC

NUVENTUS NV.C™ Multi-unit Final Coping is connected to the endosseous dental implant via multi-unit abutment and are indicated for use as an aid in prosthetic rehabilitations in fully or partially edentulous patients with bridges or full-arch prostheses.

VI. PERFORMANCE DATA

Summary of non-clinical data submitted to demonstrate substantial equivalence included

- Non-clinical worst-case MRI review to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods, J.G. Delfino, and S. Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," *Journal of Testing and Evaluation*, Volume 49 (2): 783–795), based on the entire system including all variations (prosthetic components, and fixation screws) and material composition, and the rationale addressed parameters per the FDA guidance Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, including magnetically induced displacement force and torque;
- For the proposed devices supplied sterile, sterilization testing conducted to validate the gamma irradiation sterilization process to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VD_{max}^{25}, according to ISO 11137-1 and ISO 11137-2; bacterial endotoxin testing including *Limulus* amebocyte lysate (LAL) test according to ANSI/AAMI ST72 to demonstrate that all sterile products meet a limit of < 20 EU/device; and shelf life testing of samples after accelerated aging equivalent to five (5) years of real time aging according to ASTM F1980, with testing of the packaging sterile barrier;

  For the proposed devices supplied non-sterile and must be sterilized before installation in the mouth, the steam sterilization method was validated according to ISO 17665 "Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices", using the parameters described in IFU.

- Biocompatibility testing according to ISO 10993-5 (cytotoxicity) to demonstrate that the final finished subject device components (NUVENTUS NV.C™ Prosthetic Components) will be biocompatible for their intended use;
- Mechanical testing conducted according ISO 14801:2016 to demonstrate the performance of the subject devices NUVENTUS NV.C™ Prosthetic Components in combination with compatible

NUVENTUS NV.C™ Dental Implant System have sufficient strength for their intended use according to the acceptance criteria as defined in FDA Guidance *"Endosseous Dental Implants and Endosseous Dental Implant Abutments – Performance Criteria for Safety and Performance Based Pathway"*

There was no human clinical testing required to support NUVENTUS NV.C™ Prosthetic Components as the indications for use are equivalent to the predicate devices. The non-clinical testing detailed in this submission supports the substantial equivalence.

VII. CONCLUSIONS

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

NUVENTUS NV.C™ Healing Components (Healing Abutment, Healing Cap and Cover Screw)

	Subject Device	**Predicate Device**	**Substantial Equivalence Discussion**
	Infinitum Eta Ltd. NUVENTUS NV.C™ Healing Abutment	**Nobel Biocare AB Healing abutment conical connection NP, RP (K071370** NobelActive system, only healing component part**)**	
Intended Use	NUVENTUS NV.C healing components are intended for use with NUVENTUS NV.C Dental Implants in upper or lower jaw to protect the inner configuration of the implant and maintain, stabilize, and form the soft tissue during the healing process.	Healing Abutments for conical connection are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Healing Abutment and healing cap is intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.	Similar intended use, different wording
Indication for Use	NUVENTUS NV.C™ healing components are indicated to be placed in fully or partially edentulous patients after implant placement. The healing components protect the inner configuration of the implant and form, maintain, and stabilize the soft tissue during the healing process. Healing components have a maximum duration of usage of 180 days.	Nobel Biocare's NobelActive implants are endosseous implant 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. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied. The Healing Abutments and Healing caps are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for a single tooth to full arch denture procedures	Similar indication for use, different wording
Product Code	NHA	NHA	Same product code
Prosthetic Interface Platforms	NP, RP	NP, RP	Same interface platform connection
Body Diameters (mm)	4.0, 5.0, 4.5, and 5.5	3.2, 3.6, 3.8, 5.0, 6.0	Similar range of body diameters
Transmucosal Heights (mm)	3.0, 4.0, 5.0	3.0, 5.0, 7.0	Similar range of transmucosal height, excluding 7.0mm heights
Material	Titanium alloy, Ti-6Al-4V ELI, ASTM F136	Titanium alloy, ASTM F136	Same materials
Sterilization method	Gamma irradiation	Gamma irradiation	Same sterilization method
Usage	Single-patient, single-use	Single-patient, single-use	Same single-use indication

NUVENTUS NV.C™ Healing Components; Cover Screws

	Subject Device	**Predicate Device**	**Substantial Equivalence**
	Infinitum Eta Ltd. NUVENTUS NV.C Cover Screw	**Nobel Biocare AB Cover screw conical connection NP, RP (K071370** NobelActive system, only cover screw part**)**	
Product Code	NHA	NHA	Same product code
Prosthetic Interface Platforms	NP, RP	NP, RP	Same interface platform connection
Body Diameters (mm)	NP - 3.4mm, RP – 3.9mm	NP-3.5mm, RP-3.9mm	Same
Material	Titanium alloy Ti-6Al-4V ELI, ASTM F136	Ti6AI4V	Same
Anodization	Machined surface / Anodization	Machined surface / Anodization	Same
Sterilization method	Gamma irradiation	Gamma irradiation	Same sterilization method
Usage	Single-patient, single-use	Single-patient, single-use	Same single-use indication

NUVENTUS NV.C™ Temporary Prosthetic Components (Temporary Abutments, Multi-unit Abutment Temporary Coping and Clinical Screw Abutment)

	Subject Device	**Predicate Device**	**Reference Predicate Device**	**Substantial Equivalence**
	Infinitum Eta Ltd. NUVENTUS NV.C™ Temporary Abutment	**Straumann® BLX Temporary Abutment, VITA CAD-Temp, PMMA (K220751** only Titanium alloy abutments**)**	**Nobel Biocare AB Temporary abutments and copings (K071370** NobelActive system – only temporary abutments and copings part**)**	
Intended Use	NUVENTUS NV.C™ temporary prosthetic components are intended for use with implants and abutments of the NUVENTUS NV.C™ Dental Implant System to maintain, stabilize, and shape the soft tissue during the healing process and serve as a base for temporary crown or bridge restorations placed out of occlusion.	Straumann® dental implants and abutments are intended for oral implantation to provide a support structure for connected prosthetic devices.	Temporary abutments and copings: Intended to be connected to an endosseous dental implant to support the placement of a temporary dental prosthesis.	Similar intended use, different wording
Indication for Use	NUVENTUS NV.C™ temporary prosthetic components are indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must not be placed in occlusion. Temporary prosthetic components have a maximum duration of usage of 180 days.	Straumann® temporary prosthetic components are indicated to be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase. They must not be placed in occlusion. Straumann® temporary abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of partially edentulous patients with temporary crowns and bridges.	Nobel Biocare's NobelActive implants are endosseous implant 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. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.	Similar indication for use, different wording

			Temporary abutments and copings dental implant abutments intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.	
Product Code	NHA	NHA	NHA	Same product code
Reason for Predicate	N/A	Intended use	Abutment design and intended use	Similar intended use and abutment design
Prosthetic Interface Platforms	NP, RP	Torcfit	NP, RP	Same connection platform as K071370
Body diameter (mm)	4.0 and 4.5	5 and 10	Not disclosed	N/A
Transmucosal Heights (mm)	3.0	1.5	1.5, 3.0	Same transmucosal height as K071370
Material	Titanium alloy Ti-6Al-4V ELI, ASTM F136		Titanium alloy, ASTM F136	Same material composition as K071370
Sterilization	NUVENTUS NV.C™ temporary prosthetic components are delivered non-sterile	Non-sterile	Delivered non-sterile	Same sterilization parameters as K071370, both delivered non-sterile, to be cleaned and sterilized before usage
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Same single-use indication

NUVENTUS NV.C™ Prosthetic Components; Clinical Screw (screw delivered with the Temporary Abutment)

	Subject Device	**Predicate Device**	**Substantial Equivalence**
	NUVENTUS NV.C Clinical Screw	**Nobel Biocare AB Clinical Screw CC NP/RP (K132746)**	
Material	Titanium alloy Ti-6Al-4V ELI, ASTM F136	Titanium vanadium alloy (Ti6Al4V ELI, ASTM F136)	Same
Anodization	None	None	Same

NUVENTUS NV.C™ Multi-unit Abutment

	Subject Device	Predicate Device	Substantial Equivalency
	Infinitum Eta Ltd. NUVENTUS NV.C™ Multi-Unit Abutment	**Nobel Biocare AB Multi Unit Abutment Plus (K161416)**	
Intended Use	NUVENTUS NV.C™ Multi-unit Abutments are intended to be connected to dental implants after implantation, providing a stable support structure for attached prosthetic devices.	Multi-unit abutments Plus in combination with endosseous implants are indicated for multiple unit reconstructions when screw retained prosthetics are preferred.	Similar intended use, different wording
Indication for use	NUVENTUS NV.C™ Multi-unit Abutments are indicated to be placed into NUVENTUS NV.C™ dental implants to provide a support structure for the functional and esthetic oral rehabilitation of fully or partially edentulous patients with bridges or full-arch prostheses.	Multi-Unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	Similar indication for use, different wording
Product Code	NHA	NHA	Same product code
Prosthetic Interface Platforms	NP, RP	NP, RP, WP	Same prosthetic interface platforms, but excluding WP
Body diameter (mm)	4.8 mm	4.8 mm	Same body diameter
Transmucosal Heights (mm)	1.5, 2.5, 3.5, 4.5	1.5, 2.5, 3.5, 4.5	Same transmucosal heights
Angulation Correction	0°, 17°, 30°	0°, 17°, 30°	Same angulation
Material	Titanium alloy Ti-6Al-4V ELI, ASTM F136	Titanium alloy, ASTM F136	Same material composition
Sterilization method	Gamma irradiation	Gamma irradiation	Same sterilization method
Usage	Single-patient, single-use	Single-patient, single-use	Same single-use indication

NUVENTUS NV.C™ Final Prosthetic Components

<table>
<tr><th></th><th>Subject Device
Infinitum Eta Ltd.
NUVENTUS NV.C™ Multi-Unit Abutment Final Coping</th><th>Predicate Device
Straumann
Multi-base abutment coping Ti
(K113410)</th><th>Substantial Equivalency</th></tr>
<tr><td>Intended Use</td><td>NUVENTUS NV.C™ final prosthetic components are intended for oral implantation to provide a support structure for connected prosthetic devices. Final copings are fixed to abutments in order to provide support for prosthetic reconstructions such as bridges and bar-retained overdentures.</td><td>Straumann® dental implants and abutments are intended for oral implantation to provide a support structure for connected prosthetic devices.</td><td>Similar intended use, different wording</td></tr>
<tr><td>Indication for use</td><td>NUVENTUS NV.C™ Multi-unit Final Coping is connected to the endosseous dental implant via multi-unit abutment and are indicated for use as an aid in prosthetic rehabilitations in fully or partially edentulous patients with bridges or full-arch prostheses.</td><td>Prosthetic components directly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The specific indications for use for each device table are specified in the table below.
<table>
<tr><th></th><th colspan="3">Indications for use</th></tr>
<tr><th>Device type (as indicated on product label)</th><th>crown</th><th>bridge</th><th>overdentures</th></tr>
<tr><td>Anatomic abutment
Cementable Abutment
Solid abutment
synOctaQD Milling Cylinder
synOcta abutment
Meso Abutment</td><td></td><td>x</td><td>x</td></tr>
<tr><td>Multi-base Abutment Coping, Ti</td><td></td><td>x</td><td>x</td></tr>
<tr><td>synOcta@ 1.5 abutment</td><td>x</td><td>x</td><td>x</td></tr>
<tr><td>Temporary Coping
Post for temporary restoration
Temporary Coping</td><td>x</td><td>x</td><td></td></tr>
</table>
Temporary abutments, copings and protective caps are indicated for temporary usage of up to 180 days (Ti, TAN, PEEK). Temporary copings made from PMMA are intended for temporary usage up to 30 days.</td><td>Similar indication for use, different wording</td></tr>
<tr><td>Product Code</td><td>NHA</td><td>NHA</td><td>Same product code</td></tr>
<tr><td>Prosthetic Interface Platforms</td><td>NP, RP</td><td>NP, RP, WP</td><td>Same prosthetic interface platforms, but excluding WP</td></tr>
<tr><td>Body diameter (mm)</td><td>D 4.8 mm,</td><td>D 4.6mm</td><td>Same</td></tr>
<tr><td>Post Height (mm)</td><td>10.7mm</td><td>11mm</td><td>Same</td></tr>
<tr><td>Material</td><td>Titanium alloy Ti-6Al-4V ELI, ASTM F136</td><td>Titanium alloy, ASTM F136</td><td>Same material composition</td></tr>
<tr><td>Sterilization</td><td>non-sterile</td><td>non-sterile</td><td>Same sterilization parameters, both delivered non-sterile, to be cleaned and sterilized before usage</td></tr>
<tr><td>Usage</td><td>Single-patient, single-use</td><td>Single-patient, single-use</td><td>Same single-use application</td></tr>
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