



November 1, 2018

Nobel Biocare AB  
% Charlemagne Chua  
Senior Regulatory Affairs Manager  
Nobel Biocare USA LLC  
22715 Savi Ranch Parkway  
Yorba Linda, California 92887

Re: K180899

Trade/Device Name: Universal Base Abutment  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: Class II  
Product Code: NHA, PNP  
Dated: September 26, 2018  
Received: September 27, 2018

Dear Charlemagne Chua:

This letter corrects our substantially equivalent letter of October 31, 2018.

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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,

**Andrew I. Steen -S**

for Tina Kiang, Ph.D.  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K180899

Device Name

Universal Base Abutment

### Indications for Use (Describe)

The Universal Base Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Universal Base Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

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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A.4. 510(k) Summary

I. SUBMITTER

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Submitted by:  
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22715 Savi Ranch Parkway  
Yorba Linda, CA 92887

Contact Person: Charlemagne Chua, Senior Regulatory Affairs Manager  
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Date Prepared: October 25, 2018

II. DEVICE

Name of Device: Universal Base Abutment  
Common or Usual Name: Endosseous Dental Implant Abutment  
Classification Name: Endosseous Dental Implant (21 CFR 872.3630)  
Regulatory Class: II  
Primary Product Code: NHA  
Secondary Product Code: PNP

III. PREDICATE DEVICE

Primary Predicate  
K031719, Nobel Biocare - Esthetic Zirconia Abutment

Reference Devices

K153645, Vita Zahnfabrik H. Rauter GmbH Co – Vita Enamic® Implant Solutions (IS)  
K111421, Sirona Dental Systems GmbH – Sirona Dental CAD/CAM System  
K181359, Implant Direct Sybron Manufacturing LLC – Interactive Smartbase Abutments  
K151455, 3Shape A/S – 3Shape Abutment Designer Software  
K130436, Multilink Hybrid Abutment Cement – Ivoclar Vivadent, Inc.

#### IV. DEVICE DESCRIPTION

The Universal Base Abutment is a dental implant abutment intended to be used with the current Nobel Biocare dental implants that have the existing external hex style connections.

The Universal Base Abutment features a fixed upper shape with indexing feature that is intended to serve as the platform for an in-laboratory CAD/CAM system made mesostructure. The fixed upper shape and indexing feature facilitates the use of CAD/CAM systems by providing a known shape that can be imported into the design software, thereby, simplifying the CAD/CAM design process.

The Universal Base Abutment is available for the Nobel Biocare Narrow Platform (NP), Regular Platform (RP) and Wide Platform (WP) for external hex. All sizes are available in either 1.5 or 3mm collar heights. The Universal Base Abutment is made of titanium vanadium alloy.

The digital workflow requires the use of the following equipment:

- Scanner: 3Shape intra oral scanner Trios (3Shape A/S)
- Design Software: 3Shape Abutment Designer Software (3Shape A/S) - K151455
- Restorative Material: Enamic (Vita Zahnfabrik H. Rauter GmbH Co) - K153645
- Milling Unit: CORiTEC, imes-core milling unit

The following restorative design specifications is required:

| Restorative design specifications for Universal Base |                                                 |
|------------------------------------------------------|-------------------------------------------------|
| Parameter                                            | Specification                                   |
| Angle from axis of the implant                       | 20° Max                                         |
| Wall Thickness Circular                              | 0.8mm min.                                      |
| Wall Thickness Margin                                | 0.275mm min.                                    |
| Post Height                                          | 5.2mm min.                                      |
| Maximum Length, width and Height                     | EM-14 blank 12x14x18mm<br>EM-10 blank 8x10x15mm |

#### V. INDICATIONS FOR USE

The Universal Base Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Universal Base Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital

dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

## VI. Comparison of Technological Characteristics

| Technological characteristics |                                | Subject Device                                                                                                | Primary Predicate                                                                                                                                                                                        | Reference Device                                                                                                                                                                                                                                                                                           | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                      | Reference Device                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------|--------------------------------|---------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                               |                                | Universal Base Abutment                                                                                       | Esthetic Zirconia Abutment (K031719)                                                                                                                                                                     | VITA ENAMIC IS (K153645)                                                                                                                                                                                                                                                                                   | Sirona Dental CAD/CAM-System (K111421)                                                                                                                                                                                                                                                                                                                                                                                                | InterActive SMARTBase Abutments (K181359)                                                                                                                                                                                                                                                                                                             |
| Design Features               | Compatible Implant Platform    | Nobel Biocare<br><br>External Hex<br>Narrow Platform (NP)<br>Regular Platform (RP)<br>Wide Platform (WP)      | Nobel Biocare<br>Internal Tri -Channel<br>Narrow Platform (NP)<br>Regular Platform (RP)<br>Wide Platform (WP)<br><br>External Hex<br>Narrow Platform (NP)<br>Regular Platform (RP)<br>Wide Platform (WP) | Nobel Biocare<br>Internal Tri-Channel<br>Narrow Platform (NP)<br>Regular Platform (RP)<br>Wide Platform (WP)<br>6.0<br><br>External Hex<br>Narrow Platform (NP)<br>Regular Platform (RP)<br><br>Internal Conical Connection<br>Narrow Platform (NP)<br>Regular Platform (RP)<br><br>and Table 1 of K153645 | The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Branemark (K022562), Friadent Xive (K013867), Biomet 3i Osseotite (K980549), Astra Tech Osseospeed (K091239), Zimmer Tapered Screw-Vent (K061410), Straumann Synocta (K061176), Straumann Bone Level (K053088), Biomet 3i Certain (K014235), Nobel Biocare Active (K071370). | InterActive SMARTBase abutments are compatible at the implant level with InterActive (3.0mm and 3.4mm Platform) and SwishActive (3.0mm and 3.4mm Platform) system implants.                                                                                                                                                                           |
|                               | Ti-base Material               | Titanium vanadium alloy (ASTM F136)                                                                           | Metal adapter for Internal Tri-Channel: CP titanium grade 1 (ASTM F67)                                                                                                                                   | Titanium vanadium alloy (ISO 5832-3)                                                                                                                                                                                                                                                                       | Tibase - Titanium 6AL4V                                                                                                                                                                                                                                                                                                                                                                                                               | Titanium                                                                                                                                                                                                                                                                                                                                              |
|                               | Mesostructure / Crown Material | Enamic (K153645)                                                                                              | Y-TZP zirconium oxide (ISO 13356)                                                                                                                                                                        | VITA ENAMIC IS, identical in composition to Enamic (K153645)                                                                                                                                                                                                                                               | Cercon HT                                                                                                                                                                                                                                                                                                                                                                                                                             | Zenostar MT                                                                                                                                                                                                                                                                                                                                           |
|                               | Abutment Design                | 2 piece – Enamic (K153645) bonded to Universal Base Abutment mounted on to the implant and fixed with a screw | External Hex: Single piece with fixed upper shape<br><br>Internal Tri-Channel: Single piece with fixed upper shape and Metal adapter                                                                     | 2 piece – VITA ENAMIC IS bonded to Sirona TiBase (K111421) mounted on to the implant and fixed with a screw                                                                                                                                                                                                | The TiBase is a premanufactured prosthetic component directly connected to endosseous dental implants with a screw and is intended for use as an aid in prosthetic rehabilitation.                                                                                                                                                                                                                                                    | Abutment body consisting of a titanium base and supplied with a fixation screw. The bases are provided with straight, angled, and modified zirconia tops for patient specific devices. The devices are also provided without a zirconia top and a superstructure or hybrid crown or bridge can be milled to fit the bases intended to be manufactured |

| Technological characteristics |                             | Subject Device                                                                                         | Primary Predicate                     | Reference Device                                                                | Reference Device                                                                | Reference Device                                                                              |
|-------------------------------|-----------------------------|--------------------------------------------------------------------------------------------------------|---------------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
|                               |                             | Universal Base Abutment                                                                                | Esthetic Zirconia Abutment (K031719)  | VITA ENAMIC IS (K153645)                                                        | Sirona Dental CAD/CAM-System (K111421)                                          | InterActive SMARTBase Abutments (K181359)                                                     |
|                               |                             |                                                                                                        |                                       |                                                                                 |                                                                                 | at Implant Direct Manufacturing facility.s                                                    |
|                               | Abutment Fixation           | Screwed                                                                                                | Screwed                               | Screwed                                                                         | Screw or Cement Retained                                                        | Screw Retained                                                                                |
|                               | Maximum Abutment Angulation | 20°                                                                                                    | No angulation                         | 20°                                                                             | 20°                                                                             | 30°                                                                                           |
|                               | Design Workflow             | 3Shape intra oral scanner Trios (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) - K151455 | Traditional workflow                  | Sirona software – inlab 15.0 and above<br>Sirona software – CEREC 4.4 and above | Sirona software – inlab 15.0 and above<br>Sirona software – CEREC 4.4 and above | 3M Tru-Definition, I Tero Scanner<br>3Shape Abutment Designer Software (3Shape A/S) - K151455 |
|                               | Manufacturing Workflow      | CORiTEC milling unit (imes-icore)                                                                      | Traditional workflow                  | Sirona CEREC milling systems                                                    | Sirona CEREC milling systems                                                    | Wieland-Zenotec Select & Zenotec CAM                                                          |
|                               | Mechanical Testing          | Dynamic Fatigue Testing per ISO 14801                                                                  | Dynamic Fatigue Testing per ISO 14801 | Dynamic Fatigue Testing per ISO 14801                                           | -                                                                               | Dynamic Fatigue Testing per ISO 14801                                                         |



| Technological characteristics | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Primary Predicate                                                                                                                                                                              | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Reference Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                               | Universal Base Abutment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Esthetic Zirconia Abutment (K031719)                                                                                                                                                           | VITA ENAMIC IS (K153645)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Sirona Dental CAD/CAM-System (K111421)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | InterActive SMARTBase Abutments (K181359)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Indications for Use           | <p>The Universal Base Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.</p> <p>The Universal Base Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment.</p> <p>he system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.</p> | Nobel Biocare's Esthetic Zirconia Abutment is indicated for the treatment of partially edentulous patients requiring prosthetic devices and/or endosseous implants to restore chewing function | VITA ENAMIC Implant Solutions is indicated for use as a component of a two-piece abutment system, consisting of a TiBase component, and a mesostructure or abutment crown. VITA ENAMIC Implant Solutions is intended for use in partially or fully edentulous mandible or maxillae for fabrication of permanent, anterior or posterior, single unit CAD/CAM abutments. VITA ENAMIC Implant Solutions is indicated for use in conjunction with the CAD/CAM component of the Sirona Dental CAD/CAM system and the following TiBase abutments and implant bodies: (Table 1 of K153645) | The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. | InterActive/SmishActive Implant System consists of 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 SMARTBase abutment support for fixed bridgework. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The SMARTBase Abutments consist of two major parts. Specifically, the titanium base and zirconia top components make up a two-piece abutment. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. Narrow Diameter (3.2, 3.3mm) Implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization. |

## Analysis of Differences Between Subject Device and Predicates

The Universal Base Abutment and Esthetic Zirconia Abutment primary predicate (K031719) are intended to be used with the same existing Nobel Biocare dental implant connection external hex style connection. The Universal Base Abutment is a two-piece abutment made of titanium vanadium alloy and Enamic (K153645) while the primary predicate K031719 is a one-piece, composed of zirconium oxide, or two-piece abutment/crown, composed of CP titanium and zirconium oxide, depending on the implant connection.

The Universal Base Abutment and reference device VITA ENAMIC IS (K153645) are both abutment systems intended to fit the Nobel Biocare dental implants. Both systems consist of a titanium abutment component and a mesostructure or abutment crown composed of Enamic (K153645) material. Furthermore, both systems feature a screwed abutment fixation. The Universal Base Abutment allows for a maximum abutment angulation correction of 20 degrees as the reference device VITA ENAMIC IS (K153645) which also allows for a maximum abutment angulation correction of 20 degrees. Furthermore, both systems are intended for CAD/CAM workflows. The reference device K153645 utilizes the Sirona Dental CAD/CAM-System (K111421) which includes scanner, software and mill to manufacture the Enamic (K153645) mesostructure. The Universal Base Abutment utilizes a 3shape TRIOS intraoral scanner, 3Shape Abutment Designer Software (3Shape A/S) - K151455) and a CORiTEC imes-icore milling unit to produce the mesostructure.

The Universal Base Abutment and reference device InterActive SMARTBase Abutments (K181359) are both abutment systems intended to fit the Nobel Biocare dental implants. The Universal Base Abutment consist of a titanium abutment component and a mesostructure or abutment crown composed of Enamic (K153645) material. The InterActive SMARTBase Abutments (K181359) consists of a titanium abutment component and a mesostrucutre or abutment crown composed of Zirconia. Both systems feature a screwed abutment fixation. The Universal Base Abutment allows for a maximum abutment angulation correction of 20 degrees and the the reference device InterActive SMARTBase Abutments (K181359) allows for systems are intended for CAD/CAM workflows. The reference device K181359 utilizes the 3M Tru-Definition, ITero Scanner System scanner, 3Shape Abutment Designer Software (3Shape A/S) - K151455) and a Wieland-Zenotec Select and Zenotec CAM unit to produce the Zirconia mesostructure. The Universal Base Abutment utilizes the 3shape TRIOS intraoral scanner, 3Shape Abutment Designer Software (3Shape A/S) - K151455) and a CORiTEC imes-icore milling unit to produce the mesostructure.

### Compatible Implant Platforms

The Universal Base Abutment is designed to connect directly to the Nobel Biocare dental implants. The placement of the Universal Base Abutment takes place after placement of the dental implant. The reference device VITA ENAMIC IS (K153645)

Ti-base is intended to be connected directly to the implant. Unlike the subject device where it is intended to be used with Nobel Biocare dental implants only, the predicate VITA ENAMIC IS (K153645) is intended to be used with Nobel Biocare dental implants as well as other implants made by non-Vita manufacturers.

#### Design Workflow

The design and fabrication of the Enamic (K153645) restorations to be bonded to the Universal Base Abutment will be conducted using the following workflow: 3shape TRIOS intraoral scanner, 3Shape Abutment Designer Software (3Shape A/S) - K151455) and a CORiTEC imes-icore milling unit. The reference device InterActive SMARTBase Abutments (K181359) utilizes a different scanner but the same software to design the restoration.

#### Manufacturing Workflow

The manufacturing of the of the Enamic (K153645) restorations to be bonded to the Universal Base Abutment will be milled with a CORiTEC imes-icore milling unit. The reference device InterActive SMARTBase Abutments (K181359) utilizes Wieland-Zenotec Select and Zenotec CAM to produce the milled abutment component. The workflow which includes the 3shape TRIOS oral scanner, 3Shape Abutment Designer Software (3Shape A/S) - K151455) and the CORiTEC imes-icore milling machine. The manufacturing workflow differing with the milling unit does not impact demonstrating the substantial equivalence of the subject device to the predicates.

#### Indications for Use

The intended use for both the subject and predicate device are in the table above. The Universal Base Abutment is a two-piece abutment system, consisting of a titanium premanufactured stock component, and a mesostructure or abutment crown which is designed and fabricated with a CAD/CAM workflow. The reference abutments (K153645 and K181359) are also two-piece abutment systems, consisting of a titanium premanufactured stock component and a mesostructured or abutment crown which is fabricated with a CAD/CAM workflow. The difference does not impact demonstrating the substantial equivalence of the subject device to the predicates.

#### Summary:

The design differences between the subject and predicates do not raise different questions of substantial equivalence. Differences in technology were evaluated through performance testing.

## VII. PERFORMANCE DATA

The following performance testing was submitted in this 510(k) to support substantial equivalence:

### Mechanical Testing

Worst case dynamic fatigue testing per ISO 14801 demonstrating compliance with the minimum required fatigue properties of the Universal Base Abutment with a bonded Enamic mesostructure. Results confirmed that the proposed Universal Base Abutments were equivalent to the predicate devices.

#### Biocompatibility Testing

Biological evaluation was conducted according to ISO 10993-1. Cytotoxicity testing per ISO 10993-5 was conducted on the finished devices. GC-MS analysis was performed to qualify any organic leachables/ extractables according to CEN EN ISO 10993 12 and CEN EN ISO 10993-18. Results indicate that the devices met biocompatibility requirements for its intended use.

#### Software Verification and Validation

Validation was completed on the Universal Base Abutment with the 3Shape TRIOS Scanner, 3Shape Abutment Designer Software (K155415), CORiTEC imes-icore milling unit workflow. Software verification and validation testing was provided for the subject abutment design library to demonstrate use with the 3Shape Abutment Designer™ Software (K151455). Software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the mesostructure component outside of design limitations, including screenshots under user verification testing. In addition, the encrypted abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library.

#### Sterilization Validation

The proposed devices are provided non-sterile and intended to be steam sterilized by the end user. Steam sterilization analysis was performed following AAMI-TIR30, ISO 17665-1, and ISO 17665-2.

#### Device Packaging

Since the subject device does not represent a new worst case in terms of device packaging and shelf life, data from the predicate was leveraged as follows: The packaging for the subject device is the same as the predicate. This is a thermoform tray with peel top lid. Therefore, no additional testing was required.

### VIII. CONCLUSIONS

The Universal Base Abutment was evaluated for substantial equivalence using standard and/or comparative testing. In cases where the Universal Base Abutment could be demonstrated as not to represent the worst-case with respect to the predicates, data from these predicate devices was leveraged to support the subject device. Based on technological characteristics and non-clinical test data included in this submission, the Universal Base Abutment has been shown to be substantially equivalent to the predicates.