



December 9, 2025

Dentsply Sirona
Laura Sobrin
Sr. Technical RA Manager
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K252343
Trade/Device Name: Atlantis® Abutments in Titanium
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 25, 2025
Received: December 1, 2025

Dear Laura Sobrin:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K252343

Device Name

Atlantis® Abutments in Titanium

Indications for Use (Describe)

Atlantis Abutment & Atlantis Abutment Milling

The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.

Atlantis Crown Abutment

The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.

Atlantis Conus Abutment

The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.

Atlantis Healing Abutment

The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.

Implant Manufacturer: Dentsply Sirona

Implant System: AstraTech EV

Implant Diameter (in mm): 3.0 ((XS) Green), 3.6 ((S) Purple), 4.2 ((M) Yellow), 4.8 ((L) Blue), 5.4 ((XL) Brown)

Abutment Platform Diameter (in mm): 2.500 (XS), 2.900 (S), 3.500 (M), 4.100 (L), 4.600 (XL)

Implant System: PrimeTaper EV

Implant Diameter (in mm): 3.0 ((XS) Green), 3.6 ((S) Purple), 4.2 ((M) Yellow), 4.8, 5.4 ((L) Blue)

Abutment Platform Diameter (in mm): 2.500 (XS), 2.900 (S), 3.500 (M), 4.100 (L)

Implant System: OmniTaper EV

Implant Diameter (in mm): 3.0 ((XS) Green), 3.4 ((S) Purple), 3.8 ((M) Yellow), 4.5 ((L) Blue), 5.5 ((XL) Brown)

Abutment Platform Diameter (in mm): 2.500 (XS), 2.900 (S), 3.500 (M), 4.100 (L), 4.600 (XL)

Implant System: AstraTech EV Profile

Implant Diameter (in mm): 4.2, 4.8

Abutment Platform Diameter (in mm): 3.152 (4.2), 3.641 (4.8)

Implant System: Ankylos C/X

Implant Diameter (in mm): 3.5, 4.5, 5.5, 7

Abutment Platform Diameter (in mm): 2.520

Implant Manufacturer: MIS Implant Technologies Inc.

Implant System: M4 and Seven (NP, SP, WP)

Implant Diameter (in mm): 3.30 (NP), 3.75, 4.2 (SP), 5.0, 6.0 (WP)

Abutment Platform Diameter (in mm): 3.10 (NP), 3.536 (SP), 4.514 (WP)

Implant Manufacturer: Hiossen
Implant System: Hiossen ET III SA Fixture
Implant Diameter (in mm): 3.5 (Mini), 4.0, 4.5, 5.0, 6.0, 7.0 (Regular)
Abutment Platform Diameter (in mm): 2.797 (Mini), 3.350 (Regular)

Implant Manufacturer: Nobel Biocare
Implant System: Nobel Active/Nobel Replace Conical Connection (NP, RP, WP)
Implant Diameter (in mm): 3.5 (NP), 4.3, 5.0 (RP), 5.5 (WP)
Abutment Platform Diameter (in mm): 2.939 (NP), 3.334 (RP), 4.389 (WP)
Implant System: Nobel Replace (tri-channel connection)
Implant Diameter (in mm): 3.5 (NP), 4.3 (RP), 5.0 (WP), 6.0
Abutment Platform Diameter (in mm): 3.53 (NP), 4.30 (RP), 5.00 (WP), 5.99 (6.0)

Implant Manufacturer: Straumann
Implant System: Bone Level Cross-Fit
Implant Diameter (in mm): 3.3 (NC), 4.1, 4.8 (RC)
Abutment Platform Diameter (in mm): 2.766 (NC), 3.295 (RC)
Implant System: Standard/Standard Plus
Implant Diameter (in mm): 3.3, 4.1, 4.8 (RN), 4.8 (WN)
Abutment Platform Diameter (in mm): 4.771 (RN), 6.474 (WN)
Implant System: Standard Plus
Implant Diameter (in mm): 3.3 (NN)
Abutment Platform Diameter (in mm): 3.491

Implant Manufacturer: Zimmer Dental
Implant System: Tapered Screw-Vent
Implant Diameter (in mm): 3.7, 4.1, 4.7, 6.0
Abutment Platform Diameter (in mm): 3.536 (3.7, 4.1), 4.514 (4.7), 5.720 (6.0)
Implant System: Tapered Screw-Vent (Friction Fit)
Implant Diameter (in mm): 3.7, 4.1, 4.7, 6.0
Abutment Platform Diameter (in mm): 3.413 (3.7, 4.1), 4.385 (4.7), 5.612 (6.0)
Implant System: Screw-Vent
Implant Diameter (in mm): 3.7, 4.7
Abutment Platform Diameter (in mm): 3.536 (3.7), 4.514 (4.7)
Implant System: Screw-Vent (Friction Fit)
Implant Diameter (in mm): 3.7, 4.7
Abutment Platform Diameter (in mm): 3.413 (3.7), 4.385 (4.7)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
for
Atlantis® Abutments in Titanium (K252343)

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401, USA

Contact Person: Laura Sobrin
Telephone Number: 717-849-4434
Email: laura.sobrin@dentsplysirona.com
Date Prepared: December 5, 2025

2. Device Name:

- Proprietary Name: Atlantis® Abutments in Titanium
- Classification Name: Abutment, Implant, Endosseous, Root-Form
- CFR Number: 872.3630
- Device Class: Class II
- Primary Product Code: NHA

3. Predicate/Reference Devices:

The primary purpose of the Bundled Traditional 510(k) premarket notification is to modify the labeling of the Atlantis® Abutments in Titanium to indicate MR Conditional. This includes a total of 10 implant system compatibilities/clearances.

The predicate device, K250081, Atlantis® Abutments in Titanium, represents the latest version of the Atlantis® Abutments in Titanium and shares the same intended use, similar Indications for Use, and same design envelope as the proposed abutments.

In addition to the change in MR Conditional labeling, the submission also includes changes shared across the abutment family that were internally documented and therefore reflect the current version of the abutments, while some changes are new, generalizable changes requested to be cleared within this 510(k). Therefore, this submission proposes the same changes made in K250081 for a different group of Atlantis® Abutments in Titanium, with a few additional changes specific to the subject group of abutments. There are also some minor changes made to the abutments in this submission which were not completely covered in the K250081 clearance.

The implant system compatibilities being modified and bundled in this submission are referred to as reference devices.

Predicate Device Name – Implant system compatibility included in this submission for MR Conditional labeling update	510(k)	Product Code and Classification Reg	Company Name
Atlantis® Abutment for MIS Conical Connection Implants	K250081	NHA, Abutment, Implant, Dental, Endosseous 872.3630, Endosseous dental implant abutment	Dentsply Sirona Inc.

Reference Device Name – Implant system compatibilities bundled in this submission for MR Conditional labeling update	510(k)	Product Code and Classification Reg	Company Name
Atlantis® Abutment for MIS Implant	K172225	NHA, 872.3630	Dentsply Sirona Inc.
Atlantis® Abutment for Hiossen ET Implant	K160626	NHA, 872.3630	Dentsply Sirona Inc.
Atlantis® Abutment for Astra Tech Profile EV Implants and OsseoSpeed EV 3.0 Implants	K130999	NHA, 872.3630	Dentsply Implants Manufacturing GmbH, part of Dentsply Sirona Inc.
Astra Tech (OsseoSpeed) EV stock abutments compatible with OsseoSpeed EV implants	K111287	DZE, 872.3640 NHA, 872.3630	AstraTech AB, now Dentsply Sirona Inc.
Atlantis® Abutment for Ankylos Implant	K101004	NHA, 872.3630	Astra Tech Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for Nobel Biocare Implant	K093483	NHA, 872.3630	Astra Tech Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for Straumann Implant	K083871	NHA, 872.3630	Astra Tech Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for Nobel Replace Implant	K053654	NHA, 872.3630	Atlantis Components Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for Zimmer Implant	K053373	NHA, 872.3630	Atlantis Components Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for Straumann Implant	K050052	NHA, 872.3630	Atlantis Components Inc., now Dentsply Sirona Inc.

In addition to the above reference devices, the below reference devices are added to close the gap in technological characteristic differences between the predicate device and the proposed modified Atlantis® Abutment in Titanium implant system compatibilities.

Reference Device Name	510(k)	Product Code & Classification Reg	Company Name	Reason for inclusion
3Shape Abutment Designer Software	K151455	PNP, 872.3630	3Shape A/S	The 3Shape software is part of the additional proposed workflow that allows the user to design the Atlantis Abutment within the Atlantis design limitations prior to manufacturing by Dentsply Sirona. This workflow was cleared in K250081 and this submission proposes to expand this to the abutments

Reference Device Name	510(k)	Product Code & Classification Reg	Company Name	Reason for inclusion
				bundled in this submission.
PrimeTaper EV Dental Implant	K210610	DZE, 872.3630	Dentsply Sirona Inc.	Includes fatigue testing of the Atlantis Abutments for EV connection (reference device K111287) with the PrimeTaper EV and AstraTech EV implant systems.
OmniTaper EV	K221094	DZE, 872.3630 NHA, 872.3630	Dentsply Sirona Inc.	Includes fatigue testing of the Atlantis Abutments for EV connection (reference device K111287) with the OmniTaper EV and AstraTech EV implant systems.
PrimeTaper EV Dental Implant (3.0)	K220841	DZE, 872.3630 NHA, 872.3630	Dentsply Sirona Inc.	Includes fatigue testing of the Atlantis Abutments for EV connection (reference device K130999) with the PrimeTaper EV 3.0 and AstraTech EV 3.0 implant systems.

4. Description of Device:

Atlantis® Abutment in Titanium refers to the following abutments that are the subject of this 510(k):

- Atlantis® Abutment,
- Atlantis® Crown Abutment,
- Atlantis® Conus Abutment, and
- Atlantis® Healing Abutment.

The Atlantis® Abutments in Titanium are patient-specific dental abutments that are intended for attachment to dental implants in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The design of the Atlantis® Abutments in Titanium is derived from patient dental models and is completed by Dentsply Sirona using computer-assisted design (CAD) technology according to the clinician's prescription. The final CAD design of the Atlantis® Abutment in Titanium is fabricated using computer-assisted manufacturing (CAM) to produce a customized, patient-specific device. Design and fabrication of the Atlantis® Abutment in Titanium is completed in internal Dentsply Sirona manufacturing facilities.

Alternatively, the CAD design, according to the clinician's prescription, can be performed by a laboratory or clinician in an FDA cleared abutment design software (3Shape Abutment Designer Software, K151455) within the design envelope of the Atlantis® Abutments which is codified in the validated and locked design library of the cleared software. Fabrication of the Atlantis® Abutment is then completed in internal Dentsply Sirona manufacturing facilities.

The Atlantis® Abutment in Titanium serves as a connection of the prosthetic construction and the endosseous implant. The lower part of the abutment is designed to fit with the specific implant geometry it is compatible, and the upper part design is according to the patient's specific anatomy. The Atlantis® Abutment, including the Conus abutments and Healing abutments, are available in Titanium or Gold-shaded Titanium (titanium nitride layer applied using PVD (Physical Vapor Deposition)). The Crown Abutment is only available in Titanium.

The Atlantis® Abutment design envelope became the basis for the other more specific designs that make up the Atlantis® Abutments in Titanium. The Atlantis® Abutment is intended for use with an endosseous implant and for single tooth restoration.

The Atlantis® Crown Abutment in Titanium incorporates a design that is a combination of an abutment and an anatomically accurate crown to constitute the final finished device. It functions as a substructure that also serves as the final abutment, in a partially or completely edentulous patient.

The Atlantis® Conus abutment supports a removable prosthesis (bridges and overdentures) which is retained by friction fit to the abutment. The abutment connects to the prosthesis via caps embedded in the prosthesis.

The Atlantis® Healing Abutment is used with the compatible implants for temporary use during soft tissue healing after one-stage and two-stage surgeries. It is designed based on the planned final Atlantis® Abutment or Atlantis® Crown Abutment, using the same emergence profile as those abutments to achieve an aesthetic outcome during the soft tissue healing phase.

Unless otherwise noted in this summary, the design envelope has remained unchanged from the previously cleared systems. Parameters such as gingival height and abutment diameter are dependent on the different implant system compatibilities.

Table 4.1 below includes the main specifications of the Atlantis® Abutments in Titanium that are subject of this submission.

Table 4.1: List of specifications of proposed abutments

Item	Specification
Atlantis® Abutment in Titanium for MIS implants	
Abutment platform diameter	Ø 3.10, 3.536, 4.514 mm
Compatible Implant diameter	Ø 3.30, 3.75, 4.2, 5.0, 6.0 mm
Compatible Implant System	MIS M4 and SEVEN implants (K040807, K103089, K180282)
Connection	Internal Hexagon Connection
Atlantis® Abutment in Titanium for Hiossen ET implants	
Abutment platform diameter	Ø 2.797, 3.350 mm
Compatible Implant diameter	Ø 3.5, 4.0, 4.5, 5.0, 6.0, 7.0 mm
Compatible Implant System	Hiossen Implant System (K140934)
Connection	Internal Hexagon Connection
Atlantis® Abutment in Titanium for AstraTech Profile EV implants and OsseoSpeed EV 3.0 implants	
Abutment platform diameter	Ø 2.500 (EV), 3.152, 3.641 (Profile EV) mm
Compatible Implant diameter	Ø 3.0 (EV), 4.2, 4.8 (Profile EV) mm
Compatible Implant System	Astra Tech Profile EV implants (K130999) Astra Tech EV 3.0 implants (K120414) OmniTaper EV 3.0 implants (K221094) PrimeTaper EV 3.0 Implants (K220841)
Connection	Internal Conical Connection
Atlantis® Abutment in Titanium for OsseoSpeed EV implants	
Abutment platform diameter	Ø 2.900, 3.500, 4.100, 4.600 mm
Compatible Implant Diameter	Ø 3.6, 4.2, 4.8, 5.4 mm (AstraTech EV and PrimeTaper EV Implants) Ø 3.4, 3.8, 4.5, 5.5 mm (OmniTaper EV implants)

Item	Specification
Compatible Implant System	AstraTech EV (K120414) PrimeTaper EV (K210610) OmniTaper EV (K221094)
Connection	Internal Conical Connection
Atlantis® Abutment in Titanium for Ankylos implants	
Abutment platform diameter	Ø 2.520 mm
Compatible Implant Diameter	Ø 3.5, 4.5, 5.5, 7 mm
Compatible Implant System	Ankylos X (indexed) Implant (K083805) Ankylos C (non-indexed) Implant (K083805)
Connection	Internal connection (specifically with a 6-spline anti-rotation feature)
Atlantis® Abutment in Titanium for Nobel Biocare implants	
Abutment platform diameter	Ø 2.939 (NP), 3.334 (RP), 4.389 (WP) mm
Compatible Implant Diameter	Ø 3.5 (NP), 4.3 (RP), 5.0 (RP), 5.5 (WP) mm
Compatible Implant System	Nobel Active Internal Connection Implant (K071370) Nobel Replace Conical Connection Implant (K073142)
Connection	Internal Conical Connection
Atlantis® Abutment in Titanium for Straumann implants	
Abutment platform diameter	Ø 2.766 (NC), 3.295 (RC), 3.491 (NN) mm
Compatible Implant Diameter	Ø 3.3 (NC, NN), 4.1 (RC), 4.8 (RC) mm
Compatible Implant System	Standard SLActive (K053088)
Connection	BoneLevel: Internal Square Connection NarrowNeck: External Octagon Connection
Atlantis® Abutment in Titanium for Nobel Replace implants	
Abutment platform diameter	Ø 3.53 (NP), 4.30 (RP), 5.00 (WP), 5.99 mm
Compatible Implant Diameter	Ø 3.5 (NP), 4.3 (RP), 5.0 (WP), 6.0 mm
Compatible Implant System	Nobel Replace Implants (K023113, K020646)
Connection	Internal Tri-Channel Connection
Atlantis® Abutment in Titanium for Zimmer implants	
Abutment platform diameter	Ø 3.536, 4.514, 5.720 mm (non-friction fit) Ø 3.413, 4.385, 5.612 mm (friction fit)
Compatible Implant Diameter	Ø 3.7, 4.1, 4.7, 6.0 mm
Compatible Implant System	Zimmer Dental Screw-Vent Implant System, tapered and non-tapered (K061410, K133339, K011028)
Connection	Internal Hexagon Connection
Atlantis® Abutment in Titanium for Straumann implants	
Abutment platform diameter	Ø 4.771, 6.474 mm
Compatible Implant Diameter	Ø 3.3, 4.1, 4.8 (RN with Ø 4.8 mm shoulder) Ø 4.8 (WN with Ø 6.5 mm shoulder)
Compatible Implant System	Straumann Standard, Standard Plus and Tapered Effect Regular Neck and Wide Neck implants (K171784)
Connection	Internal octagon connection

5. Intended Use and Indications for Use:

The proposed devices and the predicate device, K250081, have the same intended use. The proposed devices are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.

The Indications for Use of the proposed devices are similar to those of the predicate device. Refer to Table 5.1 for a comparison.

Table 5.2 includes additional tables that provide a comparison between the originally cleared Indications for Use and the proposed Indications for Use statement for each implant system compatibility, and a discussion on the differences.

Table 5.1: Comparison of the Intended Use/Indications for Use of the Proposed Devices Atlantis® Abutments in Titanium and the Predicate Device (K250081)

Item	Proposed Devices Atlantis® Abutments in Titanium	Predicate Device Atlantis® Abutments in Titanium (K250081)	Discussion
Intended use	Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.	Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.	Same
Indications for Use	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft</p>	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue</p>	Same except for the implant system compatibility specific information

Item	Proposed Devices Atlantis® Abutments in Titanium	Predicate Device Atlantis® Abutments in Titanium (K250081)	Discussion
	<p>tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Dentsply Sirona Implant System: AstraTech EV Implant Diameter (in mm): 3.0 ((XS) Green), 3.6 ((S) Purple), 4.2 ((M) Yellow), 4.8 ((L) Blue), 5.4 ((XL) Brown) Abutment Platform Diameter (in mm): 2.500 (XS), 2.900 (S), 3.500 (M), 4.100 (L), 4.600 (XL) Implant System: PrimeTaper EV Implant Diameter (in mm): 3.0 ((XS) Green), 3.6 ((S) Purple), 4.2 ((M) Yellow), 4.8, 5.4 ((L) Blue) Abutment Platform Diameter (in mm): 2.500 (XS), 2.900 (S), 3.500 (M), 4.100 (L) Implant System: OmniTaper EV Implant Diameter (in mm): 3.0 ((XS) Green), 3.4 ((S) Purple), 3.8 ((M) Yellow), 4.5 ((L) Blue), 5.5 ((XL) Brown) Abutment Platform Diameter (in mm): 2.500 (XS), 2.900 (S), 3.500 (M), 4.100 (L), 4.600 (XL) Implant System: AstraTech EV Profile Implant Diameter (in mm): 4.2, 4.8 Abutment Platform Diameter (in mm): 3.152 (4.2), 3.641 (4.8) Implant System: Ankylos C/X Implant Diameter (in mm): 3.5, 4.5, 5.5, 7 Abutment Platform Diameter (in mm): 2.520</p> <p>Implant Manufacturer: MIS Implant Technologies Inc. Implant System: M4 and Seven (NP, SP, WP) Implant Diameter (in mm): 3.30 (NP), 3.75, 4.2 (SP), 5.0, 6.0 (WP) Abutment Platform Diameter (in mm): 3.10 (NP), 3.536</p>	<p>healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Dentsply Sirona Implant System: OsseoSpeed/OsseoSpeed TX Implant Diameter (in mm): 3.0 (Yellow), 3.5, 4.0 (Aqua), 4.5, 5.0 (Lilac), 4.0 (Blue - Previous) Abutment Platform Diameter (in mm): 2.330 (Yellow), 2.866 (Aqua), 3.865 (Lilac), 3.368 (Blue - Previous)</p> <p>Implant Manufacturer: MIS Implant Technologies Inc. Implant System: V3 (NP, SP), C1 (NP, SP, WP) Implant Diameter (in mm): V3: 3.30 (NP), 3.90, 4.3, 5.0 (SP); C1: 3.30 (NP), 3.75, 4.2 (SP), 5.0 (WP) Abutment Platform Diameter (in mm): V3: 2.765 (NP), 3.16 (SP); C1: 2.76 (NP), 3.16 (SP), 4.01 (WP)</p> <p>Implant Manufacturer: Altatec GmbH Implant System: Conelog Screw-Line Implant Implant Diameter (in mm): 3.3, 3.8, 4.3, 5.0 Abutment Platform Diameter (in mm): 2.80 (3.3), 3.00 (3.8, 4.3), 3.80 (5.0)</p> <p>Implant Manufacturer: Nobel Biocare Implant System: NobelActive Implant Diameter (in mm): 3.0 Abutment Platform Diameter (in mm): 2.461 Implant System: Branemark System (NP, RP, WP) Implant Diameter (in mm): 3.3 (NP), 3.75, 4.0 (RP), 5.0, 5.5 (WP) Abutment Platform Diameter (in mm): 3.476 (NP), 4.069 (RP), 5.033 (WP)</p>	

Item	Proposed Devices Atlantis® Abutments in Titanium	Predicate Device Atlantis® Abutments in Titanium (K250081)	Discussion
	<p>(SP), 4.514 (WP)</p> <p>Implant Manufacturer: Hiossen Implant System: Hiossen ET III SA Fixture Implant Diameter (in mm): 3.5 (Mini), 4.0, 4.5, 5.0, 6.0, 7.0 (Regular) Abutment Platform Diameter (in mm): 2.797 (Mini), 3.350 (Regular)</p> <p>Implant Manufacturer: Nobel Biocare Implant System: Nobel Active/Nobel Replace Conical Connection (NP, RP, WP) Implant Diameter (in mm): 3.5 (NP), 4.3, 5.0 (RP), 5.5 (WP) Abutment Platform Diameter (in mm): 2.939 (NP), 3.334 (RP), 4.389 (WP) Implant System: Nobel Replace (tri-channel connection) Implant Diameter (in mm): 3.5 (NP), 4.3 (RP), 5.0 (WP), 6.0 Abutment Platform Diameter (in mm): 3.53 (NP), 4.30 (RP), 5.00 (WP), 5.99 (6.0)</p> <p>Implant Manufacturer: Straumann Implant System: Bone Level Cross-Fit Implant Diameter (in mm): 3.3 (NC), 4.1, 4.8 (RC) Abutment Platform Diameter (in mm): 2.766 (NC), 3.295 (RC) Implant System: Standard/Standard Plus Implant Diameter (in mm): 3.3, 4.1, 4.8 (RN), 4.8 (WN) Abutment Platform Diameter (in mm): 4.771 (RN), 6.474 (WN) Implant System: Standard Plus Implant Diameter (in mm): 3.3 (NN) Abutment Platform Diameter (in mm): 3.491</p>	<p>Implant Manufacturer: BioHorizons Implant System: Prodigy System Internal/Tapered Internal Implant Diameter (in mm): 3.5, 4.5, 5.7 Abutment Platform Diameter (in mm): 3.434 (3.5), 4.399 (4.5), 5.644 (5.7) Implant System: Maestro Implant Diameter (in mm): 3.5, 4.0, 5.0 Abutment Platform Diameter (in mm): 3.708 (3.5), 4.242 (4.0), 5.258 (5.0)</p> <p>Implant Manufacturer: Biomet 3i Implant System: Certain, Certain Prevail, Certain XP Implant Diameter (in mm): Certain: 3.25, 4, 5, 6; Certain Prevail: 3.4, 4, 5; Certain XP: 5, 6 Abutment Platform Diameter (in mm): 3.404 (3.25, 3.4), 4.012 (4), 4.942 (5), 5.951 (6) Implant System: Osseotite Tapered and Osseotite Parallel Walled Implant Diameter (in mm): 3.25, 3.75, 4.0, 5.0, 6.0 Abutment Platform Diameter (in mm): 4.056 (3.25, 3.75, 4.0), 4.978 (5.0), 5.985 (6.0)</p>	

Item	Proposed Devices Atlantis® Abutments in Titanium	Predicate Device Atlantis® Abutments in Titanium (K250081)	Discussion
	<p>Implant Manufacturer: Zimmer Dental Implant System: Tapered Screw-Vent Implant Diameter (in mm): 3.7, 4.1, 4.7, 6.0 Abutment Platform Diameter (in mm): 3.536 (3.7, 4.1), 4.514 (4.7), 5.720 (6.0) Implant System: Tapered Screw-Vent (Friction Fit) Implant Diameter (in mm): 3.7, 4.1, 4.7, 6.0 Abutment Platform Diameter (in mm): 3.413 (3.7, 4.1), 4.385 (4.7), 5.612 (6.0) Implant System: Screw-Vent Implant Diameter (in mm): 3.7, 4.7 Abutment Platform Diameter (in mm): 3.536 (3.7), 4.514 (4.7) Implant System: Screw-Vent (Friction Fit) Implant Diameter (in mm): 3.7, 4.7 Abutment Platform Diameter (in mm): 3.413 (3.7), 4.385 (4.7)</p>		

Table 5.2: Comparison between the originally cleared Indications for Use and the proposed Indications for Use statement for each Atlantis Abutments in Titanium

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
K172225	<p>The ATLANTIS® Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS® Abutment to the endosseous implant.</p>	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p>	<p>Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design envelope exists between the internal CAD software and the 3Shape software (K151455).</p> <p>Removed incorrect statement around “The prosthesis [crown] can be cemented or screw retained to the abutment”. This</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	<p>The ATLANTIS® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS® Crown Abutment to the endosseous implant.</p> <p>The ATLANTIS® Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS® Conus Abutment to the endosseous implant.</p> <p>ATLANTIS® Abutment for MIS implant is compatible with MIS implant from MIS Implant System. MIS short implants (6mm) are to be used only with straight abutments.</p> <p>ATLANTIS® products are compatible with the implants shown in the table below.</p> <p>Implant manufacturer - MIS-IMPLANT TECHNOLOGIES INC</p> <p>Trade Name MIS Implant M4 & SEVEN Narrow Platform Abutment Platform Diameter Ø3.30 mm Implant Diameter Ø3.30 mm</p> <p>Trade Name MIS Implant M4 & SEVEN Standard Platform</p>	<p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: MIS Implant Technologies Inc. Implant System: M4 and Seven (NP, SP, WP) Implant Diameter (in mm): 3.30 (NP), 3.75, 4.2 (SP), 5.0, 6.0 (WP) Abutment Platform Diameter (in mm): 3.10 (NP), 3.536 (SP), 4.514 (WP)</p>	<p>was removed because a crown cannot be screwed to an abutment. Crowns are always cemented to an abutment.</p> <p>Added Healing Abutment indications.</p> <p>The statement related to short implants to be used with straight abutments was removed. This limitation for use is captured in the implant system Indications for Use where the short implants were cleared (K103089, K180282): “MIS short implants are to be used only with straight abutments”.</p> <p>The implant system indications and placement limitations dictate where the abutment will be placed. Therefore, the limitations for use are not repeated in the indications of the abutment.</p> <p>Correction was made to the abutment platform diameter since the original indications repeated the implant diameter measurements instead of specifically referring to the abutment platform diameter measurements. Drawings included in reference device, K172225 correctly reflect the proposed abutment platform diameter information.</p> <p>Note: The Zirconia Abutments are not proposed to be modified in this submission as this Bundled submission is limited to Atlantis Abutments in Titanium.</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	<p>Abutment Platform Diameter Ø3.75 and 4.2 mm Implant Diameter Ø3.75 and 4.2 mm</p> <p>Trade Name MIS Implant M4 & SEVEN Wide Platform Abutment Platform Diameter Ø5.0 and 6.0 mm Implant Diameter Ø5.0 and 6.0 mm</p>		
K160626	<p>The ATLANTIS™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS Abutment to the endosseous implant.</p> <p>The ATLANTTS™ Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS Crown Abutment to the endosseous implant.</p> <p>The ATLANTIS™ Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS Conus</p>	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is</p>	<p>Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design envelope exists between the internal CAD software and the 3Shape software (K151455).</p> <p>Removed incorrect statement around “The prosthesis [crown] can be cemented or screw retained to the abutment”. This was removed because a crown cannot be screwed to an abutment. Crowns are always cemented to an abutment.</p> <p>Added Healing Abutment indications.</p> <p>Correction was made to the abutment platform diameter since the original indications repeated the implant diameter measurements instead of specifically referring to the abutment platform diameter measurements. Drawings included in reference device, K160626 correctly reflect the proposed abutment platform diameter information.</p> <p>Note: The Zirconia Abutments are not</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	<p>Abutment to the endosseous implant.</p> <p>ATLANTIS™ products are compatible with the implants shown in the table below.</p> <p>Implant Manufacturer - HIOSSEN INC</p> <p>Trade Name HIOSSEN ET III SA Fixture Mini Abutment Platform Diameter Ø 3,5mm Implant Diameter Ø 3,5mm</p> <p>Trade Name HIOSSEN ET III SA Fixture Regular Abutment Platform Diameter Ø4.0, 4.5, 5.0, 6.0, 7.0 mm Implant Diameter Ø4.0, 4.5, 5.0, 6.0, 7.0 mm</p>	<p>an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Hiossen Implant System: Hiossen ET III SA Fixture Implant Diameter (in mm): 3.5 (Mini), 4.0, 4.5, 5.0, 6.0, 7.0 (Regular) Abutment Platform Diameter (in mm): 2.797 (Mini), 3.350 (Regular)</p>	<p>proposed to be modified in this submission as this Bundled submission is limited to Atlantis Abutments in Titanium.</p>
K130999	<p>The ATLANTIS™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.</p> <p>The ATLANTIS™ Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained. The abutment</p>	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely</p>	<p>Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design envelope exists between the internal CAD software and the 3Shape software (K151455).</p> <p>Removed incorrect statement around “The prosthesis [crown] can be cemented, screw retained or friction fit to the abutment”. This was removed because a crown cannot be screwed/friction fitted to an abutment. Crowns are always cemented to an abutment. Similarly, removed “The prosthesis [crown] is screw retained” from the</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	<p>screw is intended to secure the crown abutment to the endosseous implant.</p> <p>The ATLANTIS™ Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS™ Abutment to the endosseous implant.</p> <p>ATLANTIS™ Abutment, ATLANTIS™ Crown Abutment and ATLANTIS™ Conus Abutment are compatible with ASTRA TECH Implant System Profile EV.</p>	<p>edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Dentsply Sirona Implant System: AstraTech EV Implant Diameter (in mm): 3.0 ((XS) Green) Abutment Platform Diameter (in mm): 2.500 (XS)</p> <p>Implant System: PrimeTaper EV Implant Diameter (in mm): 3.0 ((XS) Green) Abutment Platform Diameter (in mm): 2.500 (XS)</p> <p>Implant System: OmniTaper EV</p>	<p>Crown Abutment indications.</p> <p>Added Healing Abutment indications.</p> <p>Specified the compatible implant diameter and abutment platform diameter to be consistent with the more recent Atlantis Abutment clearances.</p> <p>Expanded compatibility with more recently cleared Dentsply Sirona EV implants, the PrimeTaper EV (K220841) and OmniTaper EV (K221094). Fatigue testing with the Atlantis Abutments was reviewed in these implant system reference device submissions.</p> <p>Note: The Zirconia Abutments are not proposed to be modified in this submission as this Bundled submission is limited to Atlantis Abutments in Titanium.</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		<p>Implant Diameter (in mm): 3.0 ((XS) Green), Abutment Platform Diameter (in mm): 2.500 (XS)</p> <p>Implant System: AstraTech EV Profile Implant Diameter (in mm): 4.2, 4.8 Abutment Platform Diameter (in mm): 3.152 (4.2), 3.641 (4.8)</p>	
K111287	<p>Astra Tech Implant System Plus abutments are intended to be used in conjunction with the Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.</p>	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is</p>	<p>The originally cleared abutments have the same internal connection geometry as the Atlantis abutments as they are compatible with the same EV implant system.</p> <p>Fatigue testing with these abutments was reviewed in the PrimeTaper EV implant system (K210610) and the Omnitaper EV implant system (K221094) submissions. The proposed Atlantis Abutments will have the same indications as the other Atlantis Abutments and specify the implant system, implant diameter, and abutment diameter.</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		<p>an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Dentsply Sirona Implant System: AstraTech EV Implant Diameter (in mm): 3.6 ((S) Purple), 4.2 ((M) Yellow), 4.8 ((L) Blue), 5.4 ((XL) Brown) Abutment Platform Diameter (in mm): 2.900 (S), 3.500 (M), 4.100 (L), 4.600 (XL)</p> <p>Implant System: PrimeTaper EV Implant Diameter (in mm): 3.6 ((S) Purple), 4.2 ((M) Yellow), 4.8, 5.4 ((L) Blue) Abutment Platform Diameter (in mm): 2.900 (S), 3.500 (M), 4.100 (L)</p> <p>Implant System: OmniTaper EV Implant Diameter (in mm): 3.4 ((S) Purple), 3.8 ((M) Yellow), 4.5 ((L) Blue), 5.5 ((XL) Brown) Abutment Platform Diameter (in mm): 2.900 (S), 3.500 (M), 4.100 (L), 4.600 (XL)</p>	
K101004	The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely	Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	<p>edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement or screw retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.</p> <p>This device is compatible with the following manufacturers' implant systems: The titanium abutments are compatible with the Dentsply 3.5mm, 4.5mm, 5.5mm and 7.0mm Ankylos Implants.</p> <p>Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.</p>	<p>Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p>	<p>demonstrate that the same design envelope exists between the internal CAD software and the 3Shape software (K151455).</p> <p>Removed incorrect statement around “The prosthesis [crown] can be cemented or screw retained to the abutment”. This was removed because a crown cannot be screwed to an abutment. Crowns are always cemented to an abutment.</p> <p>Added Healing Abutment, Conus Abutment, and Crown Abutment indications. This abutment is not offered as a Crown Abutment. All Atlantis Abutments in Titanium share the same indications and Instructions for Use. The user will refer to the compatibility chart to confirm which abutments are available with which implant system.</p> <p>The special note was removed altogether for the following reasons:</p> <ul style="list-style-type: none"> - The language regarding surgical technique (early loading protocol) is more appropriate for the implant system indications and has therefore been removed from the abutment indications. - The highly angled abutment limitations were moved to the Contraindications section of the Instructions for Use. <p>This is consistent with changes made in the predicate device, K250081.</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		<p>Implant Manufacturer: Dentsply Sirona Implant System: Ankylos C/X Implant Diameter (in mm): 3.5, 4.5, 5.5, 7 Abutment Platform Diameter (in mm): 2.520</p>	<p>Added the abutment platform diameter information to be consistent with the more recent Atlantis Abutment clearances.</p> <p>Expansion of Atlantis Abutment offering by adding a non-indexed version (“C/” version) Atlantis Abutment compatible with the same Dentsply Sirona Ankylos implant system.</p>
K093483	<p>The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement or screw retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.</p> <p>This device is compatible with the following manufacturers' implant systems: The titanium and zirconia abutments are compatible with the Nobel Biocare's NobelActive Implants.</p>	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely</p>	<p>Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design envelope exists between the internal CAD software and the 3Shape software (K151455).</p> <p>Removed incorrect statement around “The prosthesis [crown] can be cemented or screw retained to the abutment”. This was removed because a crown cannot be screwed to an abutment. Crowns are always cemented to an abutment.</p> <p>Added Healing Abutment, Conus Abutment, and Crown Abutment indications.</p> <p>Specified the compatible implant diameter and abutment platform diameter to be consistent with the more recent Atlantis Abutment clearances. Added compatibility with the Nobel Replace Conical Connection and NobelActive</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		<p>edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Nobel Biocare Implant System: Nobel Active/Nobel Replace Conical Connection (NP, RP, WP) Implant Diameter (in mm): 3.5 (NP), 4.3, 5.0 (RP), 5.5 (WP) Abutment Platform Diameter (in mm): 2.939 (NP), 3.334 (RP), 4.389 (WP)</p>	<p>WP.</p> <p>Note: The Zirconia Abutments are not proposed to be modified in this submission as this Bundled submission is limited to Atlantis Abutments in Titanium.</p>
K083871	<p>The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.</p> <p>This device is compatible with the following manufacturers' implant systems:</p>	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment</p>	<p>Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design envelope exists between the internal CAD software and the 3Shape software (K151455).</p> <p>Removed the statement around “The prosthesis [crown] can be cement retained to the abutment”. This was removed as this is redundant since crowns are always cemented to an abutment.</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	<p>The titanium abutments are compatible with the Straumann Implants: Standard SLActive 3.3mm, 4.1mm and 4.8mm and the Straumann Narrow Neck 3.5mm</p> <p>The abutments in zirconia are compatible with the Straumann Implants: SLActive 4.1mm and 4.8mm.</p> <p>Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.</p>	<p>The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Straumann Implant System: Bone Level Cross-Fit Implant Diameter (in mm): 3.3 (NC), 4.1, 4.8 (RC) Abutment Platform Diameter (in mm): 2.766 (NC), 3.295 (RC) Implant System: Standard Plus Implant Diameter (in mm): 3.3 (NN) Abutment Platform Diameter (in mm): 3.491</p>	<p>Added Healing Abutment, Conus Abutment, and Crown Abutment indications.</p> <p>The special note was removed altogether for the following reasons:</p> <ul style="list-style-type: none"> - The language regarding surgical technique (early loading protocol) is more appropriate for the implant system indications and has therefore been removed from the abutment indications. - The highly angled abutment limitations were moved to the Contraindications section of the Instructions for Use. <p>This is consistent with changes made in the predicate device, K250081.</p> <p>Added the abutment platform diameter information to be consistent with the more recent Atlantis Abutment clearances. The Narrow Neck implant has a 3.5 mm platform diameter but a 3.3 mm implant diameter. Therefore, the indications were updated to specify the implant diameter.</p> <p>Note: The Zirconia Abutments are not proposed to be modified in this submission as this Bundled submission is limited to Atlantis Abutments in Titanium.</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
K053654	<p>The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.</p> <p>This device is compatible with the following manufacturers' implant systems: Nobel Biocare Replace Select Straight, Replace Select Straight One Stage, Replace Select Tapered and Replace Select Tapered One Stage.</p> <p>Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.</p>	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary</p>	<p>Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design envelope exists between the internal CAD software and the 3Shape software (K151455).</p> <p>Removed the statement around “The prosthesis [crown] can be cement retained to the abutment”. This was removed as this is redundant since crowns are always cemented to an abutment.</p> <p>Added Healing Abutment, Conus Abutment, and Crown Abutment indications.</p> <p>The special note was removed altogether for the following reasons:</p> <ul style="list-style-type: none"> - The language regarding surgical technique (early loading protocol) is more appropriate for the implant system indications and has therefore been removed from the abutment indications. - The highly angled abutment limitations were moved to the Contraindications section of the Instructions for Use. <p>This is consistent with changes made in the predicate device, K250081.</p> <p>Many of the implant systems that were originally cleared are discontinued. The implant systems are consolidated as</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		<p>use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Nobel Biocare Implant System: Nobel Replace (tri-channel connection) Implant Diameter (in mm): 3.5 (NP), 4.3 (RP), 5.0 (WP), 6.0 Abutment Platform Diameter (in mm): 3.53 (NP), 4.30 (RP), 5.00 (WP), 5.99 (6.0)</p>	<p>“NobelReplace (tri-channel connection)”.</p> <p>Specified the compatible implant diameter and abutment platform diameter to be consistent with the more recent Atlantis Abutment clearances.</p>
K053373	<p>The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.</p> <p>Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 umm are intended for the anterior region of the mouth and are not intended for the posterior region due to the limited strength of the implant.</p>	<p>Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely</p>	<p>Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design envelope exists between the internal CAD software and the 3Shape software (K151455).</p> <p>Removed the statement around “The prosthesis [crown] can be cement retained to the abutment”. This was removed as this is redundant since crowns are always cemented to an abutment.</p> <p>The special note was removed altogether for the following reasons:</p> <ul style="list-style-type: none"> - The language regarding surgical technique (early loading protocol) is more appropriate for the implant system indications and has therefore been removed from the abutment indications. - The highly angled abutment limitations were moved to the Contraindications section of the

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		<p>edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Zimmer Dental Implant System: Tapered Screw-Vent Implant Diameter (in mm): 3.7, 4.1, 4.7, 6.0 Abutment Platform Diameter (in mm): 3.536 (3.7, 4.1), 4.514 (4.7), 5.720 (6.0) Implant System: Tapered Screw-Vent (Friction Fit) Implant Diameter (in mm): 3.7, 4.1, 4.7, 6.0 Abutment Platform Diameter (in mm): 3.413 (3.7, 4.1), 4.385 (4.7), 5.612 (6.0) Implant System: Screw-Vent Implant Diameter (in mm): 3.7, 4.7 Abutment Platform Diameter (in mm): 3.536 (3.7), 4.514 (4.7) Implant System: Screw-Vent (Friction Fit) Implant Diameter (in mm): 3.7, 4.7 Abutment Platform Diameter (in mm): 3.413 (3.7), 4.385 (4.7)</p>	<p>Instructions for Use. This is consistent with changes made in the predicate device, K250081.</p> <p>Added Healing Abutment, Conus Abutment, and Crown Abutment indications.</p> <p>Specified the compatible implant system, implant diameter, and abutment platform diameter to be consistent with the more recent Atlantis Abutment clearances.</p> <p>Expansion of Atlantis Abutment offering by adding a friction-fit version Atlantis Abutment compatible with the same Zimmer Dental implant system.</p>
K050052	The Atlantis Abutment is intended for use as	Atlantis Abutment & Atlantis Abutment	Added Atlantis Abutment Milling to the

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	<p>an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.</p>	<p>Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.</p> <p>Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.</p> <p>Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.</p> <p>Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment</p>	<p>Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design envelope exists between the internal CAD software and the 3Shape software (K151455).</p> <p>Removed the statement around “The prosthesis [crown] can be cement retained to the abutment”. This was removed as this is redundant since crowns are always cemented to an abutment.</p> <p>Added Healing Abutment, Conus Abutment, and Crown Abutment indications.</p> <p>Specified the compatible implant system, implant diameter, and abutment platform diameter to be consistent with the more recent Atlantis Abutment clearances</p>

510(k)	Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		<p>screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.</p> <p>Implant Manufacturer: Straumann Implant System: Standard/Standard Plus Implant Diameter (in mm): 3.3, 4.1, 4.8 (RN), 4.8 (WN) Abutment Platform Diameter (in mm): 4.771 (RN), 6.474 (WN)</p>	

6. Technological Comparison:

The primary purpose of the Bundled Traditional 510(k) premarket notification is to modify the labeling of the Atlantis® Abutments in Titanium to indicate MR Conditional. The Abutments will be changed from MR Not Evaluated to MR Conditional which is consistent with the predicate device (K250081). The labeling change reflects the requirements in the FDA guidance document, “Testing and Labeling Devices for Safety in the Magnetic Resonance (MR) Environment” and ensures that the clinician has the necessary information to communicate to the patient regarding the MR Safety of the proposed devices.

In addition to the change in MR Conditional labeling, the submission also includes changes shared across the abutment family that were internally documented and therefore reflect the current version of the abutments, while some changes are new, generalizable changes requested to be cleared within this 510(k). Therefore, this submission proposes the same changes made in K250081 for a different group of Atlantis® Abutments in Titanium, with a few additional changes specific to this group of abutments.

Angulated Screw Access (ASA)

The Angulated Screw Access (ASA) feature is added to some Atlantis® Abutments, as cleared in the predicate device, K250081. The angulated screw access allows the clinician to access the screw access channel from the lingual side, which facilitates the installation procedure of the abutment.

Healing, Conus and Crown Abutment offering

Atlantis® Healing Abutments, Conus Abutments, and Crown Abutments were added to some interfaces that were not originally cleared with this offering. This offering is already cleared in the predicate device, K250081. The additional abutments (Healing, Conus, and Crown) are within the design envelope of the corresponding cleared Atlantis® Abutment and have the same mating geometry to the implant, which has been tested per ISO 14801.

Expanded Compatibility and Abutment variants

The Atlantis® Abutments in Titanium were expanded to be compatible with additional implant systems with the same interface connections as originally cleared, to have larger size abutments compatible with existing implant system compatibilities, and to have new options (friction-fit/interference type, additional index positioning type) abutments compatible with the same implant systems. Where applicable, when the expansion has the potential to modify the worst-case construct for fatigue testing, comparative performance testing is included in the submission to support the expansion.

Modification to Abutment Dimensions

Modification to abutment dimensions was triggered by new metrology data, improved clearance between implant, abutment and screw, and more efficient manufacturability. Where applicable, when the change has the potential to modify the worst-case construct for fatigue testing, comparative performance testing is included in the submission to support the modification.

Modification to Screws

Minor modification was made to some of the abutment screws since the original clearance of the Atlantis® Abutments in Titanium. These changes were made to standardize dimensions across the various custom abutment screws to simplify the procurement and quality control process. Upon review, the changes to the screws did not cause an interference with the internal geometry of the abutment and the modified screws are considered as safe and effective as the predicate device and reference device screws.

Atlantis Abutment Milling (Design in 3Shape)

Most reference devices in this submission are proposed to be designed by the user via 3Shape (3Shape Abutment Designer Software, K151455), which is already an option for the predicate device. With this option, after the abutment is designed by a lab, the abutment is then manufactured by Dentsply Sirona. This proposed workflow is also referred to as Atlantis® Abutment Milling.

The design envelope that is locked in the 3Shape abutment library is the same design envelope locked in the internal DS CAD system called Virtual Abutment Design (VAD). To ensure that the same design envelope present in the 3Shape Atlantis® Abutment library match those in the internal CAD system, and that the design envelope cannot be exceeded, validation was performed in the same manner as the predicate device. The software validation confirms that expanding the option of using the 3Shape design module for design of the proposed Atlantis® Abutments does not raise new questions of safety and performance.

Reprocessing

Minor modifications were made to the reprocessing steps to be followed by the end user to match the predicate device. Reprocessing validation submitted in the predicate device submission is included by reference and confirms the adequacy of the modified instructions.

The proposed Atlantis® Abutments in Titanium have the same intended use and similar Indications for Use as compared to the predicate device. The abutments labeling is modified to conform to FDA guidance document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" and align with the predicate device. Testing performed on the worst-case Dentsply Sirona implant products validates the labeling change to indicate MR Conditional and was provided in the predicate device submission and included by reference.

In addition to the MR labeling change which is the main purpose of this submission, additional internally documented changes and proposed changes were reviewed against the predicate (K250081) and reference devices (K172225, K160626, K130999, K111287, K101004, K093483, K083871, K053654, K053373, and K050052) and the changes do not raise new questions about safety and performance. Test data submitted in the predicate device is included by reference and additional testing included in this submission verifies and validates the changes to the proposed devices and the results support a conclusion of substantial equivalence.

Table 6.1: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for MIS Implants, predicate device Atlantis® Abutments in Titanium (K250081), and reference device Atlantis® Abutment for MIS Implants (K172225)

Item	Modified Atlantis® Abutment for MIS implants	Reference device, Atlantis® Abutment for MIS implants (K172225)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Same
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same offering as the predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Titanium: Ø 3.10 (NP), 3.536 (SP), 4.514 (WP) mm	Titanium: Ø 3.10 (NP), 3.536 (SP), 4.514 (WP) mm Zirconia: Ø 3.413 (SP), 4.385 (WP) mm	Ø2.330 to 5.985 mm	Same as reference device
Compatible Implant Diameter	Titanium: Ø 3.30 (NP), 3.75, 4.2 (SP), 5.0, 6.0 (WP) mm	Titanium: Ø 3.30, 3.75, 4.2, 5.0, 6.0 mm Zirconia: Ø 3.75, 4.2, 5.0, 6.0 mm	Ø3.0 to 6.0 mm	Same as reference device
Compatible Implant System	MIS M4 and SEVEN implants (K040807, K103089, K180282)	MIS M4 and SEVEN implants (K040807, K103089)	MIS V3 (K163349), MIS C1 (K172505) Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and OsseoSpeed TX (K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous) (K041492) BioHorizons Internal (K042429) Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235,	Same as reference device, with the addition of K180282 which modified the MIS (part of Dentsply Sirona) M4 and SEVEN implants. All three implant systems have the same internal hex connection. Compatibility remains unchanged.

Item	Modified Atlantis® Abutment for MIS implants	Reference device, Atlantis® Abutment for MIS implants (K172225)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
			K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458) BioHorizons External (K972313) Branemark (K974828, K022562)	
Connection	Internal Hexagon Connection	Internal Hexagon Connection	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	6.5 mm	6 mm	Same as predicate device. Different from reference device, however in K172225 the tested abutment maximum width from the implant axis was below 6.0 mm.
Minimum abutment width from implant axis	1.3525 mm	1.65 mm	1.3525 mm	Same as predicate device. Different from reference device, however in K172225 the worst-case abutment that was tested was within the minimum abutment width from the implant axis.
Minimum abutment post height	4 mm	4 mm	4 mm	Same
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue) Zirconia	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same

Item	Modified Atlantis® Abutment for MIS implants	Reference device, Atlantis® Abutment for MIS implants (K172225)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Screw type:	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as predicate device
Screw access angulation	Straight or angled up to 30°	Straight	Straight or angled up to 30°	Same as predicate device
Screw drive feature	Hex Hexalobular	Hex	Hex Hexalobular Unigrip	Same as predicate device (Hex and Hexalobular)
MR Safety	MR Conditional	MR Not Evaluated	MR Conditional	Same as predicate device

Table 6.2: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for Hiossen ET Implants, predicate device Atlantis® Abutments in Titanium (K250081), and reference device Atlantis® Abutment for Hiossen ET Implants (K160626)

Item	Modified Atlantis® Abutment for Hiossen ET implants	Reference device, Atlantis® Abutment for Hiossen ET implants (K160626)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Same
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same offering as the predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Titanium: Ø 2.797 (Mini), 3.350 (Regular) mm	Titanium and Zirconia: Ø 2.80, 3.35 mm	Ø 2.330 to 5.985 mm	Similar to the reference device. Although the nominal abutment interface diameter may have changed slightly, it is still within the tolerance of the originally cleared abutment.
Compatible Implant Diameter	Titanium: Ø 3.5 (Mini), 4.0, 4.5, 5.0, 6.0, 7.0 (Regular) mm	Titanium and Zirconia: Ø 3.5, 4.0, 4.5, 5.0, 6.0, 7.0 mm	Ø 3.0 to 6.0 mm	Same as reference device
Compatible Implant	Hiossen Implant System (K140934)	Hiossen Implant System (K140934)	MIS V3 (K163349), MIS C1 (K172505)	Same as reference device

Item	Modified Atlantis® Abutment for Hiossen ET implants	Reference device, Atlantis® Abutment for Hiossen ET implants (K160626)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
System			Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and OsseoSpeed TX (K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous) (K041492) BioHorizons Internal (K042429) Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458) BioHorizons External (K972313) Branemark (K974828, K022562)	
Connection	Internal Hexagon Connection	Internal Hexagon Connection	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	6.5 mm	6 mm	Same as predicate device. Different from reference device, however in K160626 the tested abutment maximum width from the implant axis was below 6.0 mm.
Minimum abutment width from implant axis	1.3525 mm	1.65 mm	1.3525 mm	Same as predicate device. Different from reference device, however in K160626 the worst-case abutment that

Item	Modified Atlantis® Abutment for Hiossen ET implants	Reference device, Atlantis® Abutment for Hiossen ET implants (K160626)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
				was tested was within the minimum abutment width from the implant axis.
Minimum abutment post height	4 mm	4 mm	4 mm	Same
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue) Zirconia	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type:	Straight screw	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as reference device
Screw access angulation	Straight	Straight	Straight or angled up to 30°	Same as reference device
Screw drive feature	Hex	Hex	Hex Hexalobular Unigrip	Same as reference device
MR Safety	MR Conditional	MR Not Evaluated	MR Conditional	Same as predicate device

Table 6.3: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for Astra Tech Profile EV Implants and OsseoSpeed EV 3.0 Implants, predicate device Atlantis® Abutments in Titanium (K250081), and reference device Atlantis® Abutment for Astra Tech Profile EV Implants and OsseoSpeed EV 3.0 Implants (K130999)

Item	Modified Atlantis® Abutment for Astra Tech Profile EV implants and OsseoSpeed EV 3.0 implants	Reference device, Atlantis® Abutment for Astra Tech Profile EV and OsseoSpeed EV 3.0 implants (K130999)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Same
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same offering as the predicate device. The additional offering is within the same design

Item	Modified Atlantis® Abutment for Astra Tech Profile EV implants and OsseoSpeed EV 3.0 implants	Reference device, Atlantis® Abutment for Astra Tech Profile EV and OsseoSpeed EV 3.0 implants (K130999)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
				envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Titanium EV: Ø 2.500 ((XS) Green) mm Titanium Profile EV: 3.152 (4.2), 3.641 (4.8) mm	Titanium EV: Ø 2.50 mm Titanium Profile EV: 3.153, 3.641 mm Zirconia Profile EV: 3.153, 3.641 mm	Ø2.330 to 5.985 mm	Similar. Minor changes in abutment diameter compatible with the Ø 4.2 implant. Verification and validation activities in Design Controls confirm continued compatibility and applicability of existing fatigue testing.
Compatible Implant Diameter	Titanium EV: Ø 3.0 ((XS) Green) mm, Titanium Profile EV: 4.2, 4.8 mm	Titanium EV: Ø 3.0 mm, Titanium Profile EV: 4.2, 4.8 mm Zirconia Profile EV: Ø 4.2, 4.8 mm	Ø3.0 to 6.0 mm	Same as reference device
Compatible Implant System	Astra Tech Profile EV implants (K130999) Astra Tech EV 3.0 implants (K120414) OmniTaper EV 3.0 implants (K221094) PrimeTaper EV 3.0 implants (K220841)	Astra Tech Profile EV implants (K130999) Astra Tech EV 3.0 implants (K120414)	MIS V3 (K163349), MIS C1 (K172505) Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and OsseoSpeed TX (K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous) (K041492) BioHorizons Internal (K042429) Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458) BioHorizons External (K972313) Branemark (K974828, K022562)	Added compatibility with OmniTaper and PrimeTaper EV 3.0 implants. Fatigue testing results show similar results compared to the Astra Tech EV 3.0 implants.

Item	Modified Atlantis® Abutment for Astra Tech Profile EV implants and OsseoSpeed EV 3.0 implants	Reference device, Atlantis® Abutment for Astra Tech Profile EV and OsseoSpeed EV 3.0 implants (K130999)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	6.5 mm	6 mm	Same as predicate device. Different from reference device, however in K130999 the tested abutment maximum width from the implant axis was below 6.0 mm.
Minimum abutment width from implant axis	1.3525 mm	1.65 mm	1.3525 mm	Same as predicate device. Different from reference device, however in K130999 the worst-case abutment that was tested was within the minimum abutment width from the implant axis.
Minimum abutment post height	4 mm	4 mm	4 mm	Same
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue) Zirconia	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type:	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as predicate device
Screw access angulation	Straight or angled up to 30°	Straight	Straight or angled up to 30°	Same as predicate device

Item	Modified Atlantis® Abutment for Astra Tech Profile EV implants and OsseoSpeed EV 3.0 implants	Reference device, Atlantis® Abutment for Astra Tech Profile EV and OsseoSpeed EV 3.0 implants (K130999)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Screw drive feature	Hex Hexalobular	Hex	Hex Hexalobular Unigrip	Same as predicate device (Hex and Hexalobular)
MR Safety	MR Conditional	MR Not Evaluated	MR Conditional	Same as predicate device

Table 6.4: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for OsseoSpeed EV Implants, predicate device Atlantis® Abutments in Titanium (K250081), reference device OsseoSpeed EV stock abutments compatible with OsseoSpeed EV Implants (K111287), and reference device Atlantis® Abutment for OsseoSpeed EV 3.0 implants (K130999)

Item	Modified Atlantis® Abutment for OsseoSpeed EV implants	Reference device, OsseoSpeed EV stock abutments compatible with OsseoSpeed EV implants (K111287)	Reference device, Atlantis® Abutment for OsseoSpeed EV 3.0 implants (K130999)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Same as predicate device and reference device (K130999). Friction fit added with the Atlantis Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Stock Abutments (OsseoSpeed Plus Abutments (TiDesign Abutments) and Healing Abutments)	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as predicate device. The Atlantis abutments for OsseoSpeed EV implants have the same connection and diameters as the stock abutments cleared in K111287. The difference lies in the top part of the Atlantis abutment which is customized per patient. The Atlantis Abutments for OsseoSpeed EV implants have the same design envelope and same type of connection as the reference device K130999 (3.0), except that the available diameters have been expanded (3.6/3.4, 4.2/3.8, 4.8/4.5, 5.4/5.5). Fatigue testing reviewed in K210610 (PrimeTaper EV) and K221094 (OmniTaper EV) support performance.

Item	Modified Atlantis® Abutment for OsseoSpeed EV implants	Reference device, OsseoSpeed EV stock abutments compatible with OsseoSpeed EV implants (K111287)	Reference device, Atlantis® Abutment for OsseoSpeed EV 3.0 implants (K130999)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Titanium EV (mm): Ø 2.900 ((S) Purple), 3.500 ((M) Yellow), 4.100 ((L) Blue), 4.600 ((XL) Brown)	Titanium EV: Ø 2.9, 3.5, 4.1 mm	Titanium EV: Ø 2.50 mm	Ø2.330 to 5.985 mm	Same as reference device (K111287) except that the Atlantis abutment compatible with the AstraTech EV 5.4 mm implant was added via internal documentation when the larger implant size was added to the implant product portfolio. This additional size does not represent a new worst case per ISO 14801 and FDA Guidance document.
Compatible Implant Diameter	AstraTech EV (mm): Ø 3.6 ((S) Purple), 4.2 ((M) Yellow), 4.8 ((L) Blue), 5.4 ((XL) Brown) PrimeTaper EV (mm): Ø 3.6 ((S) Purple), 4.2 ((M) Yellow), 4.8, 5.4 ((L) Blue) OmniTaper EV (mm): Ø 3.4 ((S) Purple), 3.8 ((M) Yellow), 4.5 ((L) Blue), 5.5 ((XL) Brown)	Ø 3.6, 4.2, 4.8 mm (AstraTech EV implants)	Titanium EV: Ø 3.0 mm (AstraTech EV implants)	Ø3.0 to 6.0 mm	Similar to the reference device (K111287). Fatigue testing reviewed in K210610 (PrimeTaper EV) and K221094 (OmniTaper EV) support performance.
Compatible Implant System	AstraTech EV (K120414) PrimeTaper EV (K210610) OmniTaper EV (K221094)	OsseoSpeed Plus Implants (K111287) *OsseoSpeed Plus was later rebranded as Osseospeed EV.	Astra Tech EV 3.0 implants (K120414)	MIS V3 (K163349), MIS C1 (K172505) Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and	Similar to the reference devices. Addition of the PrimeTaper EV and OmniTaper EV implants, which both have the same EV connection as the AstraTech EV implants. The AstraTech EV implant system was originally cleared in K111287, with modifications

Item	Modified Atlantis® Abutment for OsseoSpeed EV implants	Reference device, OsseoSpeed EV stock abutments compatible with OsseoSpeed EV implants (K111287)	Reference device, Atlantis® Abutment for OsseoSpeed EV 3.0 implants (K130999)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
		Osseospeed Plus Implants and AstraTech EV implants refer to the same implant system.		OsseoSpeed TX (K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous) (K041492) BioHorizons Internal (K042429) Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458) BioHorizons External (K972313) Branemark (K974828, K022562)	made in K120414.
Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference devices (K111287, K130999).
Abutment angulation	Straight, Up to 30°	Straight, Up to 20°	Straight, Up to 30°	Straight, Up to 30°	Same as the reference device (K130999) and predicate device.
Maximum abutment	15 mm	N/A – not a custom abutment	15 mm	15 mm	Same as the reference device (K130999) and predicate device.

Item	Modified Atlantis® Abutment for OsseoSpeed EV implants	Reference device, OsseoSpeed EV stock abutments compatible with OsseoSpeed EV implants (K111287)	Reference device, Atlantis® Abutment for OsseoSpeed EV 3.0 implants (K130999)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
height					
Maximum abutment width from implant axis	6 mm	N/A – not a custom abutment	6.5 mm	6 mm	Same as predicate device. Fatigue testing performed is within the design envelope.
Minimum abutment width from implant axis	1.3525 mm	N/A – not a custom abutment	1.65 mm	1.3525 mm	Same as predicate device. Fatigue testing performed is within the design envelope.
Minimum abutment post height	4 mm	N/A – not a custom abutment	4 mm	4 mm	Same as the reference device (K130999) and predicate device. Same as predicate device. Fatigue testing performed is within the design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy	Titanium alloy, Gold Shaded Titanium (Gold Hue) Zirconia	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same as the reference device (K130999) and predicate device. The proposed, predicate, and reference devices are all made of Titanium per ASTM F136.
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type:	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as predicate device
Screw access angulation	Straight or angled up to 30°	Straight	Straight	Straight or angled up to 30°	Same as predicate device
Screw drive feature	Hex Hexalobular	Hex	Hex	Hex Hexalobular Unigrip	Same as predicate device (Hex and Hexalobular)
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	MR Conditional	Same as predicate device

Table 6.5: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for Ankylos Implants, predicate device Atlantis® Abutments in Titanium (K250081) and reference device Atlantis® Abutment for Ankylos Implants (K101004)

Item	Modified Atlantis® Abutment for Ankylos implants	Reference device, Atlantis® Abutment for Ankylos implants (K101004)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment. A non-indexed version (“C/” version) Atlantis Abutment compatible with the same Dentsply Sirona Ankylos C/X implant system was also introduced.
Abutments	Atlantis Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Within the range of the predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Titanium: Ø 2.520 mm	Titanium: Ø 2.54 mm	Ø2.330 to 5.985 mm	Similar to the reference device. The proposed abutment specifications are narrower and within the tolerance of the reference device.
Compatible Implant Diameter	Ø 3.5, 4.5, 5.5, 7 mm	Ø 3.5, 4.5, 5.5, 7 mm	Ø3.0 to 6.0 mm	Same as reference device
Compatible Implant System	Ankylos C/X Implant System (K083805)	Ankylos C/X Implant System (K083805)	MIS V3 (K163349), MIS C1 (K172505) Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and OsseoSpeed TX (K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous)	Same as reference device

Item	Modified Atlantis® Abutment for Ankylos implants	Reference device, Atlantis® Abutment for Ankylos implants (K101004)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
			(K041492) BioHorizons Internal (K042429) Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458) BioHorizons External (K972313) Branemark (K974828, K022562)	
Connection	Internal Connection, (specifically with a 6-spline anti-rotation feature)	Internal Connection, (specifically with a 6-spline anti-rotation feature)	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	6.5 mm	6 mm	Same as predicate device. Different from reference device, however in K101004 the tested abutment maximum width from the implant axis was below 6.0 mm.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.3525 mm	Same as predicate device. Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Same as predicate device. Added minimum abutment post height to be consistent with

Item	Modified Atlantis® Abutment for Ankylos implants	Reference device, Atlantis® Abutment for Ankylos implants (K101004)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
				more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type:	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as predicate device
Screw access angulation	Straight or angled up to 30°	Straight	Straight or angled up to 30°	Same as predicate device
Screw drive feature	Hex Hexalobular	Hex	Hex Hexalobular Unigrip	Same as predicate device (Hex and Hexalobular)
MR Safety	MR Conditional	MR Not Evaluated	MR Conditional	Same as predicate device

Table 6.6: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for Nobel Biocare Implants, predicate device Atlantis® Abutments in Titanium (K250081), and reference device Atlantis® Abutment for Nobel Biocare Implants (K093483)

Item	Modified Atlantis® Abutment for Nobel Biocare implants	Reference device, Atlantis® Abutment for Nobel Biocare implants (K093483)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction-fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as predicate device. The additional offering is within the same design envelope as the reference device.

Item	Modified Atlantis® Abutment for Nobel Biocare implants	Reference device, Atlantis® Abutment for Nobel Biocare implants (K093483)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Titanium: Ø 2.939 (NP), 3.334 (RP), 4.389 (WP) mm	Titanium and Zirconia: Ø 3.01 (NP), 3.39 (RP) mm	Ø2.330 to 5.985 mm	Similar. The proposed specifications are slightly smaller in diameter compared to the reference device. Verification and validation activities in Design Controls confirm continued compatibility and applicability of existing fatigue testing. Added the wide platform Atlantis abutment which does not constitute a new worst-case from a fatigue perspective.
Compatible Implant Diameter	Titanium: Ø 3.5 (NP), 4.3 (RP), 5.0 (RP), 5.5 (WP) mm	Titanium and Zirconia: Ø 3.5 (NP), 4.3 (RP), 5.0 (RP) mm	Ø3.0 to 6.0 mm	Same with the addition of the wide platform (5.5 mm) Nobel Biocare implant.
Compatible Implant System	Nobel Active Internal Connection Implant (K071370) Nobel Replace Conical Connection Implant (K073142)	Nobel Active Internal Connection Implant (K071370)	MIS V3 (K163349), MIS C1 (K172505) Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and OsseoSpeed TX (K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous) (K041492) BioHorizons Internal (K042429) Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458)	Similar. Expanded compatibility with the Nobel Replace Conical Connection Implants which share the same internal geometry as the Nobel Active Internal Connection Implants. Compatibility analysis was performed to ensure that compatibility remains the same.

Item	Modified Atlantis® Abutment for Nobel Biocare implants	Reference device, Atlantis® Abutment for Nobel Biocare implants (K093483)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
			BioHorizons External (K972313) Branemark (K974828, K022562)	
Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6 mm	Same as predicate device. Different from reference device but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.3525 mm	Same as predicate device. Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Same as predicate device. Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue) Zirconia	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same

Item	Modified Atlantis® Abutment for Nobel Biocare implants	Reference device, Atlantis® Abutment for Nobel Biocare implants (K093483)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Screw type:	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as predicate device
Screw access angulation	Straight or angled up to 30°	Straight	Straight or angled up to 30°	Same as predicate device
Screw drive feature	Unigrip Hexalobular	Unigrip	Hex Hexalobular Unigrip	Same as predicate device (Unigrip and Hexalobular)
MR Safety	MR Conditional	MR Not Evaluated	MR Conditional	Same as predicate device

Table 6.7: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for Straumann Implants, predicate device Atlantis® Abutments in Titanium (K250081), and reference device Atlantis® Abutment for Straumann Implants (K083871)

Item	Modified Atlantis® Abutment for Straumann implants	Reference device, Atlantis® Abutment for Straumann Implants (K083871)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction-Fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as predicate device The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Titanium: Ø 2.766 (NC), 3.295 (RC), 3.491 (External NN) mm	Titanium: Ø 2.77, 3.30 mm, External NN Zirconia: Ø 3.26 mm	Ø2.330 to 5.985 mm	Similar to the reference device. The proposed abutment specifications are narrower and within the tolerance of the reference device, K083871. The original submission did not specify the diameter of the External Narrow Neck (NN).

Item	Modified Atlantis® Abutment for Straumann implants	Reference device, Atlantis® Abutment for Straumann Implants (K083871)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Compatible Implant Diameter	Titanium (Internal): Ø 3.3 (NC), 4.1, 4.8 (RC) mm Titanium (External): Ø 3.3 (NN) mm	Titanium (Internal): Ø 3.3, 4.1, 4.8 mm Titanium (External NN): Ø 3.3 mm Zirconia: Ø 4.1, 4.8 mm	Ø3.0 to 6.0 mm	Same as reference device.
Compatible Implant System	Standard SLActive (K053088)	Standard SLActive (K053088)	MIS V3 (K163349), MIS C1 (K172505) Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and OsseoSpeed TX (K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous) (K041492) BioHorizons Internal (K042429) Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458) BioHorizons External (K972313) Branemark (K974828, K022562)	Same as reference device
Connection	BoneLevel: Internal Square Connection NarrowNeck: External Octagon Connection	BoneLevel: Internal Square Connection NarrowNeck: External Octagon Connection	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from	6 mm	5.5 mm	6 mm	Same as predicate device. Different from reference device but still within the 6 mm

Item	Modified Atlantis® Abutment for Straumann implants	Reference device, Atlantis® Abutment for Straumann Implants (K083871)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
implant axis				maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.3525 mm	Same as predicate device. Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Same as predicate device. Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue) Zirconia	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type:	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as predicate device Note: ASA feature does not apply to the External connection abutment (Narrow Neck 3.5)
Screw access angulation	Straight or angled up to 30°	Straight	Straight or angled up to 30°	Same as predicate device
Screw drive feature	SCS Hexalobular	SCS	Hex Hexalobular Unigrip	Shares the same screw drive features of both the predicate and reference devices.
MR Safety	MR Conditional	MR Not Evaluated	MR Conditional	Same as predicate device

Table 6.8: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for Nobel Replace Implants, predicate device Atlantis® Abutments in Titanium (K250081), and reference device Atlantis® Abutment for Nobel Replace Implants (K053654)

Item	Modified Atlantis® Abutment for Nobel Replace implants	Reference device, Atlantis® Abutment for Nobel Replace Implants (K053654)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as predicate device The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø 3.53 (NP), 4.30 (RP), 5.00 (WP), 5.99 (6.0) mm	Ø 3.525, 4.295, 5.000, 5.988 mm	Ø2.330 to 5.985 mm	Similar. The proposed specifications are slightly larger in diameter compared to the reference device. This constitutes a minor change in abutment diameter compatible with the Ø 3.5, 4.3 and 6.0 implants. Verification and validation activities in Design Controls confirm continued compatibility and applicability of existing fatigue testing.
Compatible Implant Diameter	Ø 3.5 (NP), 4.3 (RP), 5.0 (WP), 6.0 mm	Ø 3.5, 4.3, 5.0, 6.0 mm	Ø3.0 to 6.0 mm	Same as reference device
Compatible Implant System	Nobel Replace Implants (K023113, K020646)	Nobel Replace Implants (K023113, K020646)	MIS V3 (K163349), MIS C1 (K172505) Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and OsseoSpeed TX (K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous) (K041492) BioHorizons Internal (K042429)	Same as reference device

Item	Modified Atlantis® Abutment for Nobel Replace implants	Reference device, Atlantis® Abutment for Nobel Replace Implants (K053654)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
			Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458) BioHorizons External (K972313) Branemark (K974828, K022562)	
Connection	Internal Tri-Channel Connection	Internal Tri-Channel Connection	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6 mm	Same as predicate device. Different from reference device but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.3525 mm	Same as predicate device. Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Same as predicate device. Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.

Item	Modified Atlantis® Abutment for Nobel Replace implants	Reference device, Atlantis® Abutment for Nobel Replace Implants (K053654)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same as predicate device. Gold-shaded titanium abutments (TiN abutments) have been reviewed by the Agency during the predicate device submission as well as in earlier submissions. This corresponds to Titanium with a titanium nitride layer applied using PVD (Physical Vapor Deposition) to create a gold shade for a more esthetic outcome.
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type:	Straight screw	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as reference device
Screw access angulation	Straight	Straight	Straight or angled up to 30°	Same as reference device
Screw drive feature	Unigrip	Unigrip	Hex Hexalobular Unigrip	Same as reference device
MR Safety	MR Conditional	MR Not Evaluated	MR Conditional	Same as predicate device

Table 6.9: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for Zimmer Implants, predicate device Atlantis® Abutment in Titanium (K250081), and reference device Atlantis® Abutment for Zimmer implants (K053373)

Item	Modified Atlantis® Abutment for Zimmer implants	Reference device, Atlantis® Abutment for Zimmer implants (K053373)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction-fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Similar to predicate device. Addition of a friction-fit connection by increasing the hex flat to flat, hex diameter through hex tips and hex taper angle. The larger hex creates the interference fit connection

Item	Modified Atlantis® Abutment for Zimmer implants	Reference device, Atlantis® Abutment for Zimmer implants (K053373)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
				condition. Internally documented fatigue test results show equal or better results. Also added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as predicate device The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Non-interference; Non-friction fit (mm): Ø 3.536 (TSV: 3.7, 4.1; SV: 3.7), 4.514 (TSV/SV: 4.7), 5.720 (TSV: 6.0) Interference; Friction fit (mm): Ø 3.413 (TSV: 3.7, 4.1; SV: 3.7), 4.385 (TSV/SV: 4.7), 5.612 (TSV: 6.0)	Ø 3.536, 4.514, 5.720 mm	Ø2.330 to 5.985 mm	Same as reference device for non-interference connection. Added the interference (friction-fit) connection.
Compatible Implant Diameter	Tapered Screw Vent (TSV): Ø3.7, 4.1, 4.7, 6.0 mm Screw Vent: Ø 3.7, 4.7 mm	Ø 3.3, 3.7, 4.7, 6.0 mm	Ø3.0 to 6.0 mm	Same as reference device. The 4.1 mm and 3.7 mm implant diameters share the same Atlantis abutment compatibility. Removed compatibility with Ø 3.3 SV implant.
Compatible Implant System	Zimmer Dental Screw-Vent Implant System, tapered and non-tapered (K061410, K133339, K011028)	Zimmer Dental Screw-Vent Implant System (tapered and non-tapered) (K011028)	MIS V3 (K163349), MIS C1 (MIS V3 (K163349), MIS C1 (K172505) Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and OsseoSpeed TX	Similar. The proposed devices are compatible with the K011028, however the most recent tapered and non-tapered implant system clearances are listed. Compatibility remains unchanged as it is the same implant connection.

Item	Modified Atlantis® Abutment for Zimmer implants	Reference device, Atlantis® Abutment for Zimmer implants (K053373)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
			(K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous) (K041492) BioHorizons Internal (K042429) Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458) BioHorizons External (K972313) Branemark (K974828, K022562)	
Connection	Internal Hexagon Connection	Internal Hexagon Connection	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6 mm	Same as predicate device. Different from reference device but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.3525 mm	Same as predicate device. Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Same as predicate device. Added minimum abutment post height to be consistent with

Item	Modified Atlantis® Abutment for Zimmer implants	Reference device, Atlantis® Abutment for Zimmer implants (K053373)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
				more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same as predicate device. Gold-shaded titanium abutments (TiN abutments) have been reviewed by the Agency during the predicate device submission as well as in earlier submissions. This corresponds to Titanium with a titanium nitride layer applied using PVD (Physical Vapor Deposition) to create a gold shade for a more esthetic outcome.
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type:	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as predicate device
Screw access angulation	Straight or angled up to 30°	Straight	Straight or angled up to 30°	Same as predicate device
Screw drive feature	Hex Hexalobular	Hex	Hex Hexalobular Unigrip	Same as predicate device (Hex and Hexalobular)
MR Safety	MR Conditional	MR Not Evaluated	MR Conditional	Same as predicate device

Table 6.10: Comparison of the technological characteristics between proposed modified Atlantis® Abutment for Straumann Implants, predicate device Atlantis® Abutments in Titanium (K250081), and reference device Atlantis® Abutment for Straumann implants (K050052)

Item	Modified Atlantis® Abutment for Straumann implants	Reference device, Atlantis® Abutment for Straumann implants (K050052)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Prosthesis attachment	Screw-retained Cement-retained	Screw-retained Cement-retained	Screw-retained Cement-retained	Same as predicate device Added Friction-fit with the

Item	Modified Atlantis® Abutment for Straumann implants	Reference device, Atlantis® Abutment for Straumann implants (K050052)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
	Friction-fit		Friction Fit	introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as predicate device The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø 4.771 (RN), 6.474 (WN) mm	Ø 4.771 mm, WP	Ø2.330 to 5.985 mm	Same. Note: The original submission did not specify the diameter of the Wide Platform.
Compatible Implant Diameter	Ø 3.3, 4.1, 4.8 (RN with Ø 4.8 mm shoulder) mm Ø 4.8 mm (WN with Ø 6.5 mm shoulder)	Ø 3.3, 4.1, 4.8 (RN with Ø 4.8 mm shoulder) mm Ø 4.8 mm (WN with Ø 6.5 mm shoulder)	Ø3.0 to 6.0 mm	Same as reference device
Compatible Implant System	Straumann Standard, Standard Plus and Tapered Effect Regular Neck and Wide Neck implants (K171784)	Straumann Standard, Standard Plus and Tapered Effect Regular Neck and Wide Neck implants	MIS V3 (K163349), MIS C1 (K172505) Conelog implant system (K113779) Nobel Biocare Active Implant 3.0 (K102436) OsseoSpeed and OsseoSpeed TX (K053384, K080396, K101732) OsseoSpeed 4.0 Blue (Previous) (K041492) BioHorizons Internal (K042429) Biomet 3i (K051461, K031475) Biomet Osseotite (K983347) Biomet 3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458) BioHorizons External (K972313) Branemark (K974828, K022562)	Same as reference device. The reference device did not specify the compatible implant system clearance. Implant systems cleared in K171784, K122855, and K033984 are all compatible with the Atlantis Abutments. The most recent implant clearance is indicated as the compatible implant system.

Item	Modified Atlantis® Abutment for Straumann implants	Reference device, Atlantis® Abutment for Straumann implants (K050052)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
Connection	Internal Octagon Connection	Internal Octagon Connection	Internal Conical Connection, External Hexagon Connection, Internal Hexagon Connection, Tapered Internal Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6 mm	Same as predicate device. Different from reference device but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.3525 mm	Same as predicate device. Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Same as predicate device. Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Same as predicate device. Gold-shaded titanium abutments (TiN abutments) have been reviewed by the Agency during the predicate device submission as well as in earlier submissions. This corresponds to Titanium with a titanium nitride layer applied using PVD (Physical Vapor Deposition) to create a

Item	Modified Atlantis® Abutment for Straumann implants	Reference device, Atlantis® Abutment for Straumann implants (K050052)	Predicate device, Atlantis® Abutments in Titanium (K250081)	Discussion
				gold shade for a more esthetic outcome.
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type:	Straight screw	Straight screw	Straight screw Angulated screw – access hole on the lingual side	Same as reference device
Screw access angulation	Straight	Straight	Straight or angled up to 30°	Same as reference device
Screw drive feature	SCS	SCS	Hex Hexalobular Unigrip	Same as reference device
MR Safety	MR Conditional	MR Not Evaluated	MR Conditional	Same as predicate device

7. Non-Clinical Tests Summary and Conclusion:

To support the labeling change from MR Not Evaluated on the labeling to MR Conditional labeling, testing reviewed in the predicate device (K250081) is included by reference. The proposed Atlantis® Abutments in Titanium meet the requirements of:

- ASTM F2052-21, Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment
- ASTM F2213-17, Standard test method for measurement of magnetically induced torque on medical devices in magnetic resonance environment
- ASTM F2119-07 (2013), Standard test method for evaluation of MR image artifacts from passive implants,
- ASTM F2503-20, Standard practice for marking medical devices and other items for safety in the magnetic resonance environment,
- FDA guidance document “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment” dated October 10, 2023

There are no changes in the biocompatibility profile of the proposed devices when compared to the predicate device, K250081. Hence the biocompatibility assessment performed in the predicate device submission is included by reference. The proposed abutments meet the following requirements:

- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- FDA’s guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’”

The reprocessing of the proposed abutments is the same as the predicate device. Therefore, testing reviewed in the predicate device is included by reference. The proposed devices meet the FDA guidance document titled “Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling” and the following standards:

- AAMI ST98:2022, Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices
- AAMI TIR 12: 2020, Designing, testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- ANSI/AAMI/ISO 17665-1:2006/(R)2013, Annex D, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 14937:2009/(R)2013, Annex D (Approach 3), Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routing control of a sterilization process
- AAMI TIR12:2020, Designing, testing and labeling medical devices intended for processing by health care facilities: A guide for manufacturers
- ANSI/AAMI/ISO TIR17665-2:2009, Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO ANSI/AAMI/ISO 17665-1.

CAD/CAM Software Validation & Verification Testing:

Software validation was performed to show that the Atlantis® abutment design envelope was implemented within the 510(k) cleared abutment design software (3Shape Abutment

Designer Software, K151455).

For changes and/or expansion made to the abutments, for some implant system compatibilities, fatigue testing according to ISO 14801:2016, Dentistry – Implants – Dynamic loading test for endosseous dental implants and FDA Guidance, Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Class II Special Controls Guidance Document is included in the submission. For all other changes/expansion, the modifications do not constitute a new worst-case construct from a fatigue testing perspective and therefore the fatigue testing included in the original clearances remains valid.

The testing described above confirmed that the proposed Atlantis® Abutments in Titanium subject of this submission are substantially equivalent to the predicate device (K250081) and reference devices (K172225, K160626, K130999, K111287, K101004, K093483, K083871, K053654, K053373, and K050052) and do not raise new questions regarding safety and effectiveness.

8. Clinical Tests Summary and Conclusion:

Not applicable. There are no clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

9. Conclusion Regarding Substantial Equivalence:

The proposed Atlantis® Abutments in Titanium have the same intended use and very similar indications as the predicate device Atlantis Abutments in Titanium (K250081). The abutments labeling is modified to conform to FDA guidance document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" and testing performed on the worst-case Dentsply Sirona implant products validates the labeling change to indicate MR Conditional.

In addition to the MR labeling change which is the main purpose of this submission, additional internally documented changes and proposed changes were reviewed against the original clearance of the reference devices (K172225, K160626, K130999, K111287, K101004, K093483, K083871, K053654, K053373, K050052) and additional reference devices included for bench testing comparison (K210610, K221094, K220841), and the changes do not raise new questions about safety and effectiveness when compared with the predicate device (K250081). Many of the changes implemented on the abutments subject of this submission were implemented on the predicate device. Test data provided in the predicate device was included by reference and any additional testing included in this premarket notification verified and validated the changes to the proposed devices. Test results support a conclusion of substantial equivalence.