



November 21, 2025

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

Re: K251205

Trade/Device Name: Atlantis® Abutments in Titanium for Straumann BLX and Neodent GM Implants
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 18, 2025
Received: October 24, 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)

K251205

Device Name

Atlantis® Abutments in Titanium for Straumann BLX and Neodent GM Implants

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: Institut Straumann

Implant System: Straumann BLX

Implant Diameter (in mm): 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5

Abutment Platform Diameter (in mm): 2.69

Implant System: Neodent GM

Implant Diameter (in mm): 3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0

Abutment Platform Diameter (in mm): 3.0

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
for
Atlantis® Abutments in Titanium for Straumann BLX and
Neodent GM Implants – K251205

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: November 20, 2025

2. Device Name:

- Proprietary Name: Atlantis® Abutments in Titanium for Straumann BLX and Neodent GM Implants
- 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 expand the implant systems that the Atlantis® Abutments in Titanium are compatible with. The proposed abutments include:

1. Atlantis® Abutments in Titanium for Straumann BLX Implants
2. Atlantis® Abutments in Titanium for Neodent GM Implants

The proposed abutments are substantially equivalent to the most recently cleared Atlantis® Abutments in Titanium (K250081) in intended use, Indications for Use, and technological characteristics.

In addition, performance data on the proposed devices are compared to that of the Atlantis® Abutment for MIS Conical Connection Implants (K193529) and the Neodent GM Line Abutments (K163194), which have a similar internal conical connection and similar sizes when compared to the proposed devices.

The proposed Atlantis® Abutments are compatible with the implant systems (K173961, K191256, K210855, K212533, K163194, K180536, and K201225) which are also included as reference devices in Table 2.1 below.

Table 2.1 Predicate and Reference Devices

Type of Device	Predicate Device Name	510(k)	Product Code and Classification Reg	Company Name
Predicate Device	Atlantis® Abutments in Titanium	K250081	NHA, Abutment, Implant, Dental, Endosseous 872.3630, Endosseous dental implant abutment	Dentsply Sirona Inc.
Reference Device	Atlantis® Abutment for MIS Conical Connection Implants	K193529	NHA, 872.3630	Dentsply Sirona Inc.
Reference Device	Straumann BLX Implant System	K173961	DZE, Implant, Endosseous, Root-Form 872.3640, Endosseous dental implant NHA, 872.3630	Institut Straumann AG
Reference Device	Straumann BLX Ø3.5 mm Implants	K191256	DZE, 872.3640	Institut Straumann AG
Reference Device	Straumann BLX Implant System	K210855	DZE, 872.3640	Institut Straumann AG
Reference Device	BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants	K212533	DZE, 872.3640	Institut Straumann AG
Reference Device	Neodent Implant System and Abutments - GM Line	K163194	DZE, 872.3640 NHA, 872.3630	Applicant: JJGC Industria e Comercio de Materiais Dentarios S.A. Correspondent: Straumann USA., Inc.
Reference Device	Neodent Implant System – GM Line	K180536	DZE, 872.3640 NHA, 872.3630	Applicant: JJGC Industria e Comercio de Materiais Dentarios S.A.
Reference Device	Neodent Implant System - GM Helix Implants 7.0	K201225	DZE, 872.3640	Applicant: JJGC Industria e Comercio de Materiais Dentarios S.A. Correspondent: Straumann USA., Inc.

4. Description of Device:

The Atlantis® Abutment in Titanium for Straumann BLX and Neodent GM Implants refers to the following types of 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 and Healing abutments further described below, are available in Titanium or Gold-shaded (titanium nitride layer applied using PVD (Physical Vapor Deposition)) Titanium. The Crown Abutment which is another Atlantis® Abutment in Titanium, 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 is also a custom fabricated abutment using the same internal CAD/CAM technology. 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.

The proposed Atlantis® Abutments in Titanium for Straumann BLX Implant are compatible with the Straumann BLX Implants. This implant system is available in diameters of 3.5, 3.75, 4.0, 4.5, 5.0, 5.5 and 6.5 mm and in lengths of 8, 10, 12, 14, 16, and 18 mm all with identical mating geometry.

The proposed Atlantis® Abutments in Titanium for Neodent GM Implant are compatible

with the Neodent GM Implants. This implant system is available in diameters of 3.5, 3.75, 4.0, 4.3, 5.0, 6.0, and 7.0 mm and in lengths of 7, 8, 9, 10, 11, 11.5, 13, 15, 16, 17 and 18 mm, all with identical mating geometry.

5. Intended Use and Indications for Use:

The proposed devices and the predicate device, Atlantis® Abutments in Titanium (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 also very similar to that of the predicate device. Refer to Table 5.1 for a comparison.

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 for Straumann BLX and Neodent GM Implants	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 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>	Similar. The difference between the proposed and predicate device indications is the implant system compatibility specific information.

Item	Proposed Devices Atlantis® Abutments in Titanium for Straumann BLX and Neodent GM Implants	Predicate Device Atlantis® Abutments in Titanium (K250081)	Discussion
Indications for Use	<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: Institut Straumann Implant System: Straumann BLX Implant Diameter (in mm): 3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5 Abutment Platform Diameter (in mm): 2.69 Implant System: Neodent GM Implant Diameter (in mm): 3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0 Abutment Platform Diameter (in mm): 3.0</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: 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>	

Item	Proposed Devices Atlantis® Abutments in Titanium for Straumann BLX and Neodent GM Implants	Predicate Device Atlantis® Abutments in Titanium (K250081)	Discussion
Indications for Use		<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> <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>	

6. Technological Comparison:

This submission expands the compatibility of the Atlantis® Abutments in Titanium with Straumann BLX Implants and Neodent GM Implants.

The proposed Atlantis® Abutments in Titanium for Straumann BLX Implants and Neodent GM Implants are identical to the predicate device Atlantis® Abutments in Titanium (K250081) with respect to intended use, Indications for Use, design envelope, general principles of operation, materials, manufacturing processes, packaging, and reprocessing.

All proposed Atlantis® Abutments for Straumann BLX and Neodent GM Implants are patient-specific dental abutments fabricated using CAD/CAM technology at Dentsply Sirona manufacturing sites. Each abutment is designed according to prescription instructions from the clinician to support a screw-retained, cement-retained or friction fit prosthesis. This process is identical to that of the predicate device (K250081). Alternatively, the abutments can be designed by a clinician/lab using 3Shape Abutment Designer Software, K151455, while still being fabricated at Dentsply Sirona manufacturing sites. This is also the same as predicate device (K250081).

Differences lie in the unique implant system compatibility of the proposed abutments. While the predicate device Atlantis® Abutments in Titanium (K250081) have a platform diameter ranging from 2.330 to 5.985, the new abutments are available in diameters 2.69 mm (Straumann BLX) and Ø3.00 mm (Neodent GM), which are within the range of the predicate device (K250081) and similar as the dimensions of the reference devices (K193529, K163194).

Similarly, while the predicate device is compatible with implant diameters ranging from 3.0 to 6.0 mm, the new abutments are compatible with implant diameters ranging from 3.5 to 6.5 mm for the Straumann implant system and 3.5 to 7.0 mm for the Neodent implant system. The reference devices (K193529, K163194) have a similar range. Although the Atlantis® Abutments in Titanium for Straumann BLX and Neodent GM implants are compatible with slightly larger implants, this is similar to the range offered with the predicate and reference devices.

In addition, the proposed Atlantis® Abutments in Titanium are compatible with implants that have a unique connection. The Atlantis® Abutments in Titanium for Straumann BLX Implants are designed for compatibility with the Straumann BLX Implant Systems (K173961, K191256, K210855 and K212533) and the proposed Atlantis® Abutments in Titanium for Neodent GM Implant are designed for compatibility with the Neodent GM Implant Systems (K163194, K180536, K201225). Differences in performance due to the implant specific geometry were verified via fatigue testing and/or compatibility analysis included in the Performance Testing section of this submission, which compare the results with the reference devices, K193529 and K163194, which have a similar intended use, internal connection, and similar compatible implant and abutment size range.

An overall comparison of the technological characteristics of the proposed device, the predicate device (K250081) and the reference devices (K193529 and K163194) is contained in Table 6.1.

Table 6.1: Comparison of the technological characteristics between the proposed Atlantis® Abutments in Titanium for Straumann BLX Implants and Neodent GM Implants, the predicate device, Atlantis® Abutments in Titanium (K250081), and the reference devices, Atlantis® Abutment for MIS Conical Connection Implants (K193529) and Neodent Implant System and Abutments – GM Line (K163194)

Item	Proposed device, Atlantis® Abutments in Titanium for Straumann BLX Implants	Proposed device, Atlantis® Abutments in Titanium for Neodent GM Implants	Predicate device, Atlantis® Abutments in Titanium (K250081)	Reference device, Atlantis® Abutment for MIS Conical Connection Implants (K193529)	Reference device, Neodent Implant System and Abutments – GM Line (K163194)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Cement-retained	Same as predicate and reference device (K193529)
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	GM Universal Abutments	Same as predicate and reference device (K193529)			
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø 2.69	Ø 3.0	Ø2.330 to 5.985 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Ø 3.3 to 4.8 mm	Similar Within range of the predicate device and similar dimensions as the reference devices.
Compatible Implant Diameter	Ø 3.5, 3.75, 4.0, 4.5, 5.0, 5.5 and 6.5 mm	Ø 3.5, 3.75, 4.0, 4.3, 5.0, 6.0, and 7.0 mm	Ø3.0 to 6.0 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Ø 3.5 to 5.0 mm	Similar in range as the predicate and reference devices. The Atlantis Abutments in Titanium for Straumann BLX and Neodent GM implants are also compatible with a slightly larger implant size (6.5 mm)

Item	Proposed device, Atlantis® Abutments in Titanium for Straumann BLX Implants	Proposed device, Atlantis® Abutments in Titanium for Neodent GM Implants	Predicate device, Atlantis® Abutments in Titanium (K250081)	Reference device, Atlantis® Abutment for MIS Conical Connection Implants (K193529)	Reference device, Neodent Implant System and Abutments – GM Line (K163194)	Discussion
						and 7.0 mm).
Compatible Implant System	Straumann BLX Implant System (K173961, K191256, K210855, K212533)	Neodent GM Implant System (K163194, K180536, K201225)	<p>MIS V3 (K163349), MIS C1 (K172505)</p> <p>Conelog implant system (K113779)</p> <p>Nobel Biocare Active Implant 3.0 (K102436)</p> <p>OsseoSpeed and OsseoSpeed TX (K053384, K080396, K101732)</p> <p>OsseoSpeed 4.0 Blue (Previous) (K041492)</p> <p>BioHorizons Internal (K042429)</p> <p>Biomet 3i (K051461, K031475)</p> <p>3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402)</p> <p>Biomet Osseotite (K983347)</p> <p>Nobel Biocare Branemark System NP 3.3 (K050705)</p>	MIS V3 (K163349), MIS C1 (K172505)	Neodent GM Implant System (K163194)	<p>Different compatible implant systems. Fatigue testing on the worst-case abutments for each new implant system compatibility confirms the performance of the proposed devices when compared to the reference device (K193529).</p> <p>Same compatible implant system (reference device K163194 with the Atlantis Abutment in Titanium for Neodent GM implants)</p>

Item	Proposed device, Atlantis® Abutments in Titanium for Straumann BLX Implants	Proposed device, Atlantis® Abutments in Titanium for Neodent GM Implants	Predicate device, Atlantis® Abutments in Titanium (K250081)	Reference device, Atlantis® Abutment for MIS Conical Connection Implants (K193529)	Reference device, Neodent Implant System and Abutments – GM Line (K163194)	Discussion
			BioHorizons 3.5 (K010458) 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	Internal Conical Connection	Internal Conical Connection	Similar connection types
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Up to 30°	Same or similar
Maximum abutment height	15 mm	15 mm	15 mm	15 mm	N/A - Not a customized abutment	Same as predicate and reference device (K193529)
Maximum abutment width from implant axis	6 mm	6 mm	6 mm	6.5 mm	N/A - Not a customized abutment	Same as predicate device Note: K193529 was modified in K250081 to consolidate the design envelope.

Item	Proposed device, Atlantis® Abutments in Titanium for Straumann BLX Implants	Proposed device, Atlantis® Abutments in Titanium for Neodent GM Implants	Predicate device, Atlantis® Abutments in Titanium (K250081)	Reference device, Atlantis® Abutment for MIS Conical Connection Implants (K193529)	Reference device, Neodent Implant System and Abutments – GM Line (K163194)	Discussion
Minimum abutment width from implant axis	1.3525 mm	1.3525 mm	1.3525 mm	1.65 mm	N/A - Not a customized abutment	Same as predicate device Note: K193529 was modified in K250081 to consolidate the design envelope.
Minimum abutment post height	4 mm	4 mm	4 mm	4 mm	N/A - Not a customized abutment	Same as predicate and reference device (K193529)
Material: Abutment	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy, Gold Shaded Titanium (Gold Hue)	Titanium alloy	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type	Straight screw Angulated screw	Straight screw Angulated screw	Straight screw Angulated screw	Straight screw	Straight screw	Same as predicate device Note: K193529 was modified in K250081 to add angulated screw access.
Screw access angulation	Straight or angled up to 30°	Straight or angled up to 30°	Straight or angled up to 30°	Straight	Straight	Same as predicate device Note: K193529 was modified in K250081 to add angulated screw access.
Screw drive feature	Hex Hexalobular	Hex Hexalobular	Hex Hexalobular	Hex	Hex	Same as predicate device Note: K193529 was

Item	Proposed device, Atlantis® Abutments in Titanium for Straumann BLX Implants	Proposed device, Atlantis® Abutments in Titanium for Neodent GM Implants	Predicate device, Atlantis® Abutments in Titanium (K250081)	Reference device, Atlantis® Abutment for MIS Conical Connection Implants (K193529)	Reference device, Neodent Implant System and Abutments – GM Line (K163194)	Discussion
						modified in K250081 to add angulated screw access.
MRI Labeling	MR Conditional labeling	MR Conditional labeling	MR Conditional labeling	MR Not Evaluated	MR Not evaluated for safety and compatibility in MR environment	Same as predicate device Note: K193529 was modified in K250081 for MR Conditional Labeling.
Sterility	Non-sterile to end user	Non-sterile to end user	Non-sterile to end user	Non-sterile to end user	Sterile to end user	Same as predicate and reference device (K193529)
Reprocessing	Cleaning followed by Sterilization	Cleaning followed by Sterilization	Cleaning followed by Sterilization	Cleaning followed by Sterilization	Ethylene oxide sterilization	Same as predicate and reference device (K193529)
Overall workflow	-Import intraoral or stone model scans into 3Shape OR import into DS internal CAD design system -Export CAD design into CAM system. - Abutment is milled by DS milling center -Inspection, packaging and shipping	-Import intraoral or stone model scans into 3Shape OR import into DS internal CAD design system -Export CAD design into CAM system. -Abutment is milled by DS milling center -Inspection, packaging and shipping	-Import intraoral or stone model scans into 3Shape OR import into DS internal CAD design system -Export CAD design into CAM system. - Abutment is milled by DS milling center -Inspection, packaging and shipping	-Import intraoral or stone model scans into DS internal CAD design system -Export CAD design into CAM system. - Abutment is milled by DS milling center -Inspection, packaging and shipping	N/A - Not a customized abutment	Same as predicate device Note: K193529 was modified in K250081 to add 3Shape in the CAD design of the abutment.
Abutment Design	Design by DS in internal CAD design system	Design by DS in internal CAD design system	Design by DS in internal CAD design system	Design by DS in internal CAD design system	N/A - Not a customized abutment	Same as predicate device Note: K193529 was modified in

Item	Proposed device, Atlantis® Abutments in Titanium for Straumann BLX Implants	Proposed device, Atlantis® Abutments in Titanium for Neodent GM Implants	Predicate device, Atlantis® Abutments in Titanium (K250081)	Reference device, Atlantis® Abutment for MIS Conical Connection Implants (K193529)	Reference device, Neodent Implant System and Abutments – GM Line (K163194)	Discussion
	OR Design by lab/clinician using 3Shape Abutment Designer Software (K151455) within the confines of the Atlantis Abutment design envelope.	OR Design by lab/clinician using 3Shape Abutment Designer Software (K151455) within the confines of the Atlantis Abutment design envelope.	OR Design by lab/clinician using 3Shape Abutment Designer Software (K151455) within the confines of the Atlantis Abutment design envelope.			K250081 to add 3Shape in the CAD design of the abutment.
Abutment Manufacturing	Dentsply Sirona FDA registered facility	Dentsply Sirona FDA registered facility	Dentsply Sirona FDA registered facility	Dentsply Sirona FDA registered facility	FDA registered facility	Manufactured by FDA registered facility

7. Non-Clinical Tests Summary and Conclusion:

The proposed devices do not represent a worst-case for scanning in an MR environment and therefore the same MR testing data provided in the predicate device, K250081, is referenced in this submission. 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 included 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
- 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 for Atlantis® Abutment Milling: Software validation was performed to validate that the Atlantis® Abutment design limitations for the two new abutments were implemented within the 510(k) cleared abutment design software (3Shape Abutment Designer Software K151455).

Geometric compatibility analysis was conducted on OEM implant bodies, OEM abutments, and OEM screws to support the dimensional compatibility of the Atlantis® Abutment in Titanium for Straumann BLX implants (Ø 3.5, 3.75, 4.0, 4.5 5.0, 5.5, 6.5 mm) and Neodent GM Implants (Ø 3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0 mm).

Fatigue testing on the worst-case combination for each new implant system compatibility was performed according to the requirements of ISO 14801:2016, Dentistry – Implants – Dynamic loading test for endosseous dental implants. Fatigue testing and compatibility analysis incorporate recommendations from the FDA Guidance, Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Class II Special Controls Guidance Document.

The testing described above confirmed that the proposed Atlantis® Abutments in Titanium for Straumann BLX and Neodent GM Implants are substantially equivalent to the predicate device (K250081) and reference device (K193529) 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 for the Straumann BLX and Neodent GM Implants have the same intended use, Indications for Use, design envelope, general principles of operation, materials, manufacturing processes, packaging, and reprocessing compared to the predicate device Atlantis® Abutments in Titanium (K250081).

Geometric compatibility analysis was conducted on OEM implant bodies, OEM abutments, and OEM screws to support the dimensional compatibility of the Atlantis® Abutment in Titanium for Straumann BLX implants (Ø 3.5, 3.75, 4.0, 4.5 5.0, 5.5, 6.5 mm) and Neodent GM Implants (Ø 3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0 mm).

Differences lie in the unique geometry of the abutment connection to the implant as a result of the two new implant systems. Differences in the design were tested via fatigue testing and/or compatibility analysis to ensure that the performance and/or compatibility of the abutments are similar to the reference devices (K193529, K163194) which share the same intended use, including similar internal connection, size range, and angulation. Test data is included in this premarket notification to verify and validate the changes to the proposed devices and the results support a conclusion of substantial equivalence with the predicate device, K250081.