June 26, 2025

Open Implants, LLC
% Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K250967
Trade/Device Name: Sherlock
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 26, 2025
Received: March 31, 2025

Dear Chris Brown:

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

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

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

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250967

Device Name
Sherlock

Indications for Use *(Describe)*
Sherlock abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed CAD/CAM customizations for Sherlock abutments are to be sent to an Open Implants-validated milling center for manufacture.

Sherlock abutments are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table

Compatible Implant Systems	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
Neodent Helix GM®, Drive GM®, Titamax GM®	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	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
Sherlock
June 26, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	Open Implants, LLC 2850 Redhill Avenue, Suite 200 Santa Ana, CA 92705 Telephone: +1 781-587-3242 Fax: n/a
Official Contact	Gregg Gellman, President
Email:	ggellman@openimplants.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Sherlock
Common Name:	Abutment, Implant, Dental, Endosseous
Regulation Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Class:	Class II
Product Code:	NHA
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and technological characteristics to the following Predicate device. The Subject device shares technological characteristics with the following Reference devices.

510(k)	Predicate Device Name	Company Name
K220482	Sherlock	Open Implants, LLC
510(k)	**Reference Device Name**	**Company Name**
K212664	Sherlock	Open Implants, LLC
K193335	Sherlock	Open Implants, LLC
K163194	Neodent Implant System - GM Line	JJGC Indústria e Comércio de Materiais Dentários SA.
K180536	Neodent Implant System - GM Line	JJGC Industria e Comercio de Materiais Dentarios SA
K201225	Neodent Implant System - GM Helix Implants 7.0	JJGC Industria e Comercio de Materiais Dentarios SA
K150704	Panavia V5	Kuraray Noritake Dental, Inc.

INDICATIONS FOR USE

Sherlock abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed CAD/CAM customizations for Sherlock abutments are to be sent to an Open Implants-validated milling center for manufacture.

Sherlock abutments are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table

Compatible Implant Systems	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
Neodent Helix GM®, Drive GM®, Titamax GM®	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	3.0

DEVICE DESCRIPTION

Sherlock is a dental implant abutment system that is being expanded to include a new compatible implant system, Neodent GM®. The Subject device implant platform diameter is 3.0 mm, and the corresponding compatible implant body diameters range from 3.5 mm to 7.0 mm.

The abutment designs are Titanium Base, Titanium Blank, Straight Multi-Unit, Multi-Unit Angled 17°, and Multi-Unit Angled 30° Abutments. These abutment designs were previously cleared in the sponsor's K220482 Predicate device and K212664 Reference device submissions. All abutment designs are provided with corresponding abutment screws.

The following table shows the Subject device abutments for the Neodent GM® compatible implant platforms.

Implant Diameter (mm)	Implant Platform Diameter (mm)	Prosthetic Interface (implant/ abutment) Diameter (mm)	Subject Device Abutment Designs					
			Titanium Base (CAD/CAM	Titanium Blank (CAD/CAM)	Straight Multi-Unit (non-indexed)	17° Angulated Multi-Unit (indexed)	30° Angulated Multi-Unit (non-indexed)	Screws
3.5	3.0	2.0	X	X	X	X	X	X
3.75	3.0	2.0	X	X	X	X	X	X
4.0	3.0	2.0	X	X	X	X	X	X
4.3	3.0	2.0	X	X	X	X	X	X
5.0	3.0	2.0	X	X	X	X	X	X
6.0	3.0	2.0	X	X	X	X	X	X
7.0	3.0	2.0	X	X	X	X	X	X
Material			**Grade 23 – Titanium Ti-4Al-6V-ELI**					
Finish			None					

The Subject device Titanium Base abutments are intended to be used as a two-piece abutment composed of the base bottom-portion (prefabricated titanium base component) with a cemented/bonded CAD-CAM fabricated zirconia top-portion (superstructure) where the final two-piece abutment (base component and cemented superstructure) is the finished device used for the prosthetic restoration. Each patient-specific zirconia superstructure is individually prescribed by the clinician and manufactured by an authorized milling center.

All Subject device prefabricated titanium base components are provided in a straight design with no angulation in the titanium base post. They are provided with either an indexed/engaging implant connection for crowns or a non-engaging/nonindexed implant connections for bridges. The standard prefabricated titanium base components are provided in gingival heights ranging from 0.8 mm to 3.0 mm and abutment post lengths of 8 mm or 10 mm. The ASC prefabricated titanium base components are provided in gingival heights ranging 0.8 mm to 2.5 mm and abutment post length of 8 mm. Additional gingival height may be provided for both abutment designs in the zirconia superstructure. ASC prefabricated titanium base components are provided with a cutout in the prosthetic post to accommodate a restoration with an angled screw channel when clinically necessary. Standard prefabricated titanium base components and ASC prefabricated titanium base components posts may be reduced to 4 mm to accommodate individual patient occlusion. The zirconia mesostructure may contain an angled post within the established design parameters.

The overall design parameters for the two-part Standard and ASC CAD/CAM prefabricated titanium base components with zirconia mesostructure are:

Minimum Zirconia Wall Thickness – 0.5 mm
Minimum Post Height for single-unit abutment* – 4.0 mm
Minimum Overall Gingival Height – 0.8 mm (titanium base plus zirconia)
Maximum Overall Gingival Height – 5 mm
Maximum Correction Angle – 30°

*measured above the gingival height of the final patient-matched mesostructure design

The required cement for bonding the zirconia superstructure to the Subject device Titanium Bases to create the final two-piece abutment is Kuraray Noritake Dental PANAVIA™ V5 cleared in K150704.

Titanium Blank abutments, sometimes referred to as "Pre-mill" or "Ti-Blank" abutments are one-part abutments intended for use in a CAD/CAM workflow. Each Subject device Titanium Blank implant abutment has a pre-manufactured indexed implant connection interface with a cylindrical customization section and a milling retention geometry section. The retention geometry holds the component in a milling machine fixture while the patient-specific portion above the implant interface is milled in a dental milling machine. All patient-specific Titanium Blank abutment fabrication is by prescription on the order of the clinician.

The overall design parameters for the Titanium Blank customized abutments are:

Minimum Wall Thickness – 0.75 mm
Minimum Post Height for single-unit abutment* – 4.0 mm
Minimum Overall Gingival Height – 0.8 mm
Maximum Overall Gingival Height – 5 mm
Maximum Correction Angle – 30°

*measured above the gingival height of the final patient-matched design

All digitally designed zirconia mesostructures for use with the Subject device titanium base abutments and digitally designed Subject device titanium blank abutments will be fabricated at an Open Implants validated milling center under FDA quality system regulations.

Multi-Unit Abutments (MUAs) are intended for use with multi-unit restorations. They are considered two-part abutments. The base portion of the MUA is connected directly to the implant either with an integral screw (straight MUA) or with a separate multi-unit abutment screw (angulated abutments). Straight MUAs have a non-indexed connection with the dental implant. The angulated MUAs have an indexed connection with the dental implant. The second part of the MUA is a mating coping which is retained with a prosthetic screw. Multi-Unit Abutments are available in Straight, 17° Angulated and 30° Angulated configurations. The coping and prosthetic screw is compatible with each MUA design/configuration.

All Subject device abutments and corresponding abutment screws are pre-manufactured from Ti-6Al-4V ELI (Grade 23) titanium conforming to ASTM F136, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)* and are provided non-sterile to the user. The mesostructure/copings for Titanium base abutments are fabricated from zirconia conforming to ISO 13356, *Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

For the compatible OEM implant line, worst-case constructs of each compatible implant system in the premarket notification were subjected to static and fatigue testing according to ISO 14801 using Subject device abutments and screws.

A reverse engineering study of OEM implant bodies, abutments, and abutment screws was performed to demonstrate compatibility with the Neodent Implant System - GM Line (K163194, K180536 and K201225).

Biocompatibility cytotoxicity testing to ISO 10993-5 for the titanium base abutments is leveraged from the K220482 Predicate device and K193335 Reference device. Biocompatibility cytotoxicity testing to ISO 10993-5 for the titanium blank abutments and MUAs is leveraged from the K212664 Reference device.

Cleaning validation testing to AAMI TIR30 for titanium and zirconia constructs is leveraged from the sponsor's K220482 Predicate and K212664 Reference devices. Sterilization validation testing to ISO 17665-1 and ISO 14937 for titanium and zirconia constructs is leveraged from the sponsor's K220482 Predicate and K212664 Reference devices.

A non-clinical worst-case MRI review was performed to evaluate the sponsor's metallic previously cleared (K220482) Sherlock devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795). This MRI review was leveraged for the Subject device.

No clinical or animal testing data is included in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

Overall, the Subject device is substantially equivalent in indications and design principles to the sponsor's Predicate and Reference devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the Subject, Predicate device, and Reference devices.

The Indications for Use Statement (IFUS) of the Subject device is highly similar to the sponsor's K220482 Predicate device. The IFUSs differ only in the name(s) and sizes of the compatible implant systems. Similarly, the differences between the Subject device and sponsor's K212664 Reference device IFUSs are also related to the specific device names and compatible implant lines. These minor differences do not impact substantial equivalence because the IFUSs express the same intended use to facilitate dental prosthetic restorations.

The Indications for Use Statement (IFUS) of the Subject device is similar to the K163194, K180536 and K201225 Reference devices. The IFUSs for these Reference devices include descriptions of dental implants and other dental implant abutment designs. But this difference does not impact substantial equivalence because the IFUSs express the same intended use to facilitate dental prosthetic restorations, expressed equivalently using different specific wording.

The Subject device's technological characteristics are highly similar to the sponsor's K220482 Predicate and K212664 Reference devices with the only differences being the compatible implant systems and abutment dimensions specific to those implant systems. The sponsor's Subject, Predicate and Reference devices have the same product code/regulation. The nature of an internal implant connection, offering both engaging and non-engaging connections is the same.

The Subject device titanium base abutment designs are leveraged from the sponsor's K220482 Predicate device. The Subject device implant titanium blank abutment and multi-unit abutments designs are leveraged from the sponsor's K212664 Reference device.

The sponsors Subject, K220482 Predicate and K212664 Reference devices all support cement-retained or screw-retained prosthetic restorations both in single unit and multi-unit configurations. They share the same end-user Steam Sterilization method, biocompatibility and MR Safety classification.

The K163194, K180536 and K201225 Reference devices are leveraged for support of substantial equivalence with respect to the Neodent Implant System - GM Line implant diameters, implant/abutment connection interface, platform diameter (3.0 mm) and abutment gingival height dimensions. The Subject device offers a slightly higher gingival height (6.0 mm) for 30° angled Multi-Unit Abutments than the K163194 Reference device (5.9 mm – based on K163194 device labeling). The 6.0 mm dimension of the Subject device is supported by Bench Performance Testing.

Reverse engineering and compatibility analysis was performed to validate physical compatibility with the Neodent GM® implant connection. Additionally, fatigue testing according to ISO 14801, *Dentistry — Implants — Dynamic loading test for endosseous dental implants* was performed to validate compatibility with the Neodent GM® implants.

Minor differences in the prosthetic platform diameter dimensions and compatible implant systems between the Subject and Predicate device do not affect substantial equivalence. These minor differences do not impact safety or effectiveness as these differences are related to the compatible OEM implant designs and are mitigated by mechanical performance testing.

CONCLUSION

Overall, the Indications for Use statements are highly similar, differing only in the list of compatible implant system systems.

Overall, the Technological Characteristics, mode of operation and materials of the Subject device are substantially equivalent to that of the sponsor's Predicate and Reference devices with the only change being the compatible implant systems which are supported by the K163194, K180536, and K201225 Reference devices and bench performance testing of the Subject device.

The basis for the belief that the Subject device is substantially equivalent to the sponsor's Predicate and Reference devices and is summarized in the following comparison tables.

Table A – Comparison of Indications for Use Statement

<table>
<tr>
<th>Subject Device
Sherlock
Open Implants, LLC</th>
<th>Predicate Device
Sherlock
Open Implants, LLC
K220482</th>
<th>Reference Device
Sherlock
Open Implants, LLC
K212664</th>
<th>Reference Device
Neodent Implant System - GM Line
JJGC Indústria e Comércio de Materiais Dentários SA.
K163194</th>
<th>Reference Device
Neodent Implant System - GM Line
JJGC Indústria e Comércio de Materiais Dentários SA.
K180536</th>
<th>Reference Device
Neodent Implant System - GM Line
JJGC Indústria e Comércio de Materiais Dentários SA.
K201225</th>
</tr>
<tr>
<td>Sherlock abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed CAD/CAM customizations for Sherlock abutments are to be sent to an Open Implants-validated milling center for manufacture.

Sherlock abutments are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table
<table>
<tr><th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td>Neodent Helix GM®, Drive GM®, Titamax GM®</td><td>3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0</td><td>3.0</td></tr>
</table>
</td>
<td>Sherlock abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed CAD/CAM customizations for Sherlock abutments are to be sent to an Open Implants-validated milling center for manufacture.

Sherlock abutments are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table
<table>
<tr><th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare NobelActive®</td><td>3.5
4.3, 5.0</td><td>3.5 (NP)
3.9 (RP)</td></tr>
<tr><td>Straumann Bone Level</td><td>3.3
4.1, 4.8</td><td>3.3 (NC)
4.1, 4.8 (RC)</td></tr>
<tr><td>Zimmer TSV</td><td>3.7, 4.1
4.7
6.0</td><td>3.5
4.5
5.7</td></tr>
</table>
</td>
<td>Sherlock abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed CAD/CAM customizations for Sherlock abutments are to be sent to an Open Implants-validated milling center for manufacture.

Sherlock abutments are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table
<table>
<tr><th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td>Biomet 3i Certain</td><td>3.25
4.0
5.0
6.0</td><td>3.4
4.1
5.0
6.0</td></tr>
<tr><td>Straumann Bone Level</td><td>3.3
4.1, 4.8</td><td>3.3 (NC)
4.1, 4.8 (RC)</td></tr>
<tr><td>Zimmer TSV</td><td>3.7, 4.1
4.7
6.0</td><td>3.5
4.5
5.7</td></tr>
</table>
</td>
<td>Indications for Use for GM implants and conventional abutments:
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Indications for Use for GM Titanium Base abutments:
Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations.
All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for GM Pro Peek Abutments:
The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.</td>
<td>Indications for Use for GM Helix implants and conventional abutments:
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Indications for Use for GM Exact Titanium Block for Medentika Holder:
GM Exact Titanium Block for Medentika Holder is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. The GM Exact Titanium Block for Medentika Holder abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. All digitally designed abutments for use with the GM Exact Titanium Block for Medentika Holder are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for GM Exact Titanium Base abutments:
Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for Titanium Base C for GM Exact abutments:
The Titanium Base C for GM Exact abutments is a titanium component that is placed over Neodent implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations. All digitally designed copings and/or crowns for use with the Titanium Base C for GM Exact abutments are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.</td>
<td>The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.</td>
</tr>
</table>

Table B - Comparison of Technological Characteristics

Comparison	Subject Device Sherlock Open Implants	Predicate Device Sherlock Open Implants K220482	Reference Device Sherlock Open Implants K212664	Reference Device Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários SA. K163194	Reference Device Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários SA. K180536	Reference Device Neodent Implant System - GM Helix Implants 7.0 JJGC Industria e Comercio de Materiais Dentarios SA K201225
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate/Reference	Not Applicable	Material, sterilization, biocompatibility, abutment design, engaging and non-engaging connection	Material, sterilization, biocompatibility, abutment design, prosthesis attachment	Implants, Implant/Restorative interface	6 mm Implant compatibility, Implant/Restorative interface	7 mm Implant compatibility, Implant/Restorative interface
Product Code	NHA	NHA	NHA	DZE, NHA	DZE, NHA	DZE
Regulation	872.3630	872.3630	872.3630	872.3640	872.3640	872.3640
Abutment Design	**Prefabricated titanium base component** Material: Ti-6AL-4V ELI Alloy (Component and Screw) Zirconia (Mesostructure) Platform Diameter: 3.0 mm Minimum post height: 4.0 mm Gingival Height: 0.8 to 3 mm Prosthetic Diameter: 4.8 mm Straight Ti-Base, no post angle Post without cut-out design (Std) Post w/cut-out design for angulated screw channel (ASC) *Zirconia CAD/CAM Design Parameters* Minimum Wall Thickness: 0.5 mm Prosthetic Diameter: 4.8 to 11.9 mm Minimum post height*: 4.0 mm Post Correction Angle: 0 to 30° Total Gingival Height (including mesostructure): 0.8 to 5.0 mm *measured above the gingival height of the final patient-matched mesostructure design	**Prefabricated titanium base component** Material: Ti-6AL-4V ELI Alloy (Component and Screw) Zirconia (Mesostructure) Platform Diameter: 3.3 to 5.7 mm** Minimum post height: 4.0 mm, 5.0 mm** Gingival Height: 0.5 to 3 mm Straight Ti-Base, no post angle. Post without cut-out design (Std) Post w/cut-out design for angulated screw channel (ASC) *Zirconia CAD/CAM Design Parameters* Minimum Wall Thickness: 0.5 mm Prosthetic Diameter: 4.4 to 11.9 mm** Post Correction Angle: 0 to 30° Total Gingival Height (including mesostructure): 0.5 to 5.0 mm **varies by implant line	n/a	**Prefabricated titanium base component** Material: Ti-6AL-4V ELI Alloy (Component and Screw) Zirconia (Mesostructure) Straight Ti-Base, no post angle Platform Diameter: 3.0 mm Post Height: 4, 6 mm Prosthetic Diameter: 3.5, 4.5 mm Gingival Height: 0.8 to 4.5 mm Up to 30° Correction Angle Steam Sterilization– End-User	**Prefabricated titanium base component** Material: Ti-6AL-4V ELI Alloy (Abutment and Screw) Zirconia (Mesostructure) Straight Ti-Base, no post angle Platform Diameter: 3.0 mm Post Height: 4, 6 mm Prosthetic Diameter: 5.5 mm Gingival Height: 0.8 to 5.5 mm Up to 30° Correction Angle Steam Sterilization– End-User	n/a
	Titanium Blank Material: Grade 23 Ti Alloy (Abutment/Screw) Platform Diameter: 3.0 mm Minimum post height*: 4.0 mm Gingival Height: 0.8 to 5 mm Minimum Wall Thickness: 0.75 mm Prosthetic Diameter: 3.0 to 11.9 mm Post Correction Angle: 0 to 30° *measured above the gingival height of the final patient-matched design	n/a	**Titanium Blank** Material: Grade 23 Ti Alloy (Abutment/Screw) Platform Diameter: 3.3 to 6.0 mm** Minimum post height: 4.0 mm Gingival Height: 0.5 to 5 mm Minimum Wall Thickness: 0.41 to 0.65** Prosthetic Diameter: 3 to 11.9 mm Post Correction Angle: 0 to 30° **varies by implant line	n/a	**Titanium Blank** Material: Grade 23 Ti Alloy (Abutment/Screw) Maximum Angle - 30° Steam Sterilization– End-User	n/a
	Multi-Unit Abutment Straight Material: Grade 23 Ti Alloy (Abutment/screw) Platform Diameter: 3.0 mm Gingival Height: 0.8 to 5.5 mm Prosthetic Diameter: 4.8 mm Post Correction Angle: 0°	n/a	**Multi-Unit Abutment Straight** Material: Grade 23 Ti Alloy (Abutment/screw) Platform Diameter: 3.3 to 6.0 mm** Gingival Height: 1.0 to 5 mm Prosthetic Diameter: 4.8 mm Post Correction Angle: 0° **varies by implant line	**Multi-Unit Straight (Mini Conical)** Material: Ti Alloy (Abutment/Screw) Platform Diameter: 3.0 mm Gingival Height: 0.8 to 5.5 mm Prosthetic Diameter: 4.8 mm Post Correction Angle: 0° EtO Sterile	n/a	n/a
	Multi-Unit Abutment Angled Material: Grade 23 Ti Alloy (Abutment/Screw) Platform Diameter: 3.0 mm Gingival Height: 3.0 to 6.0 mm Prosthetic Diameter: 4.8 mm Post Correction Angle: 17, 30°	n/a	**Multi-Unit Abutment Angled** Material: Grade 23 Ti Alloy (Abutment/Screw) Platform Diameter: 3.3 to 6.0 mm** Gingival Height: 2.0 to 5.0 mm Prosthetic Diameter: 4.8 mm Post Correction Angle: 17, 30° **varies by implant line	**Multi-Unit (Mini Conical)** Material: Ti Alloy (Abutment/Screw) Platform Diameter: 3.0 mm Gingival Height: 3.9 to 5.9 mm Prosthetic Diameter: 4.8 mm Post Correction Angle: 17, 30° EtO Sterile	n/a	n/a
Abutment/Implant Interface	Internal connection, engaging and non-engaging	Internal connection, engaging and non-engaging	Internal connection, engaging	Internal connection, engaging	Internal connection, engaging	Internal connection, engaging
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained
Restoration	Single unit Multi-unit	Single unit Multi-unit	Single unit Multi-unit	Single unit Multi-unit	Single unit Multi-unit	Single unit
Sterilization - Abutment	Steam Sterilization– End-User	Steam Sterilization– End-User	Steam Sterilization– End-User	See Abutment Design above	See Abutment Design above	n/a