



June 21, 2022

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

Re: K220482
Trade/Device Name: Sherlock
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 15, 2022
Received: May 16, 2022

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <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
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)

K220482

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)
Nobel Biocare NobelActive®	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)
Straumann Bone Level	3.3	3.3 (NC)
	4.1, 4.8	4.1, 4.8 (RC)
Zimmer TSV	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

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

K220482

Sherlock

June 17, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name Open Implants, LLC
800 West Cummings Ave, Suite 4900
Woburn, MA 01801
Telephone: +1 781-587-3242
Fax: n/a

Official Contact Gregg Gellman, CEO
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
K212664	Sherlock	Open Implants, LLC

510(k)	Reference Device Name	Company Name
K193335	Sherlock	Open Implants, LLC
K212108	Dynamic TiBase	Talladium Espana

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:

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Zimmer TSV	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

DEVICE DESCRIPTION

Sherlock is a dental implant abutment system that is being expanded to include two (2) new abutment designs compatible with three (3) OEM implant systems. The Subject device implant platform diameters range from 3.3 mm to 5.7 mm, and the corresponding compatible implant body diameters also range from 3.3 mm to 6.0 mm. The Subject device includes the following two-piece abutment designs: Titanium base and Titanium Base with angulated screw channel (ASC) and are provided with corresponding abutment screws. All abutments and screws are manufactured from Ti-6Al-4V ELI alloy conforming to ASTM F136 and are provided non-sterile.

In final, finished form, the Subject device abutments are intended to be used as a two-piece abutment composed of the base bottom-portion (titanium base) with a cemented/bonded CAD-CAM zirconia top-portion. Each patient-specific zirconia superstructure is individually prescribed by the clinician and manufactured by an authorized milling center.

The following table shows the Subject device abutments for each of the Compatible implant platforms.

Sherlock Platform Diameter/ Compatible Implant System	Subject Device Abutment Designs	
	Titanium Base	ASC Titanium Base
Nobel Biocare Nobel Active®		
3.5 mm (NP)	X	X
3.9 mm (RP)	X	X
Straumann Bone Level		
3.3 mm (NC)	X	X
4.1 mm (RC)	X	X
4.8 mm (RC)	X	X
Zimmer TSV		
3.5 mm	X	X
4.5 mm	X	X
5.7 mm	X	X

All Subject device abutments are provided in a straight design with no angulation in the titanium base post and with an indexed/engaging implant connection for crowns or a non-engaging/non-indexed implant connections for bridges. The standard Titanium base abutments are provided in gingival heights ranging from 0.25 mm to 3.0 mm and abutment post lengths of 8 mm or 10 mm. The ASC Titanium Base abutments are provided in gingival heights ranging 0.8 mm to 1.8 mm and abutment post length of 8 mm. Additional gingival height may be provided for both abutment designs in the zirconia superstructure. ASC Titanium Base abutments are provided with a cutout in the prosthetic post to accommodate a restoration with an angled screw channel when clinically necessary. Standard Titanium Base and ASC Titanium Base 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.

All digitally designed zirconia copings (mesostructures) for use with the Subject device titanium base abutments will be made at an Open Implants validated milling center under FDA quality system regulations, and the zirconia material will conform to ISO 13356.

The overall design parameters for the two-part Standard and ASC CAD/CAM Titanium Base customized abutments with zirconia mesostructure are:

- Minimum Zirconia Wall Thickness – 0.5 mm
- Minimum Post Height for single-unit restoration – 4.0 mm, 5.0 mm for Straumann implant line
- Minimum Overall Gingival Height – 0.5 mm (titanium base plus zirconia)
- Maximum Overall Gingival Height – 5 mm
- Maximum Correction Angle – 30°

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

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

For each 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.

Reverse engineering studies of OEM implant bodies, abutments, and abutment screws to demonstrate compatibility with the implant systems listed in this premarket notification are leveraged from the K193335 (Nobel Active) and K212664 (Straumann Bone Level and Zimmer TSV) submissions.

Biocompatibility cytotoxicity testing to ISO 10993-5 for the titanium bases is leveraged from the K193335 Reference device.

Cleaning validation testing to AAMI TIR30 for a titanium and zirconia construct is leveraged from the K193335 Reference device. Sterilization validation testing to ISO 17665-1 and ISAO 14937 for a titanium and zirconia construct is leveraged from the K193335 Reference device.

Non-clinical worst-case MRI review was performed to evaluate the metallic 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), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment", including magnetically induced displacement force and torque.

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 Predicate device 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 substantially equivalent to that of the K212664 Predicate device. Differences in the list of compatible implant systems do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function.

Similarly, the differences between the Subject device IFUS and that of each of the Reference devices are related to the specific device names and design features, validated milling centers, and the compatible implant lines. The K212108 which includes a new abutment design technology has a similarly worded Indications for Use statement, specific to the implant system of that premarket notification. None of these minor differences impact substantial equivalence because all IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

Subject device abutments are substantially equivalent in intended use to the sponsor's K212664 Predicate device. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Reference devices introduce additional restorative interfaces, abutment designs with similar intended uses.

The Subject and K212664 Predicate devices are intended for single-unit or multi-unit restorations, have internal implant interface connections, and are made of Ti-6Al-4V ELI alloy (abutments and abutment screws) and are intended for cement-retained restorations. Biocompatibility of the Subject device is substantially equivalent to and supported by the Predicate device being fabricated from the same materials.

The Subject device includes abutment designs for implant platform diameters range from 3.3 mm to 5.7 mm, with the corresponding compatible implant body diameters ranging from 3.3 mm to 6.0 mm. Similarly, the K212664 Predicate device abutment designs supported implant platform diameters range from 3.3 mm to 6.0 mm, with the corresponding compatible implant body diameters ranging from 3.25 mm to 6.0 mm. The Subject device and K212664 Predicate devices both include abutments which may include up to a 30° post correction angle.

Compatibility with the listed implant systems is supported by the K212664 Predicate and K193335 Reference devices and through non-clinical performance testing of the Subject device.

The Subject device abutment designs are highly similar to the K212108 Reference device Titanium Base design including similar design parameters. Both the Subject and K212108 Reference devices are two-piece abutments with a titanium base and a zirconia mesostructure. Both the Subject and K212108 Reference device Titanium Base abutments have a straight titanium post with no angulation built into the post. The Subject and K212108 Reference device abutments are both offered with a cut-out portion in the post to support an angulated screwdriver access channel. The Subject device is also offered in a titanium base configuration without the cut-out portion, providing additional post surface area for cementation. The two-piece titanium base/zirconia mesostructure abutment design is supported by the K212108 Reference device.

The Subject device is to be sterilized by the end-user, using the same methods as previously validated for the sponsor's K212664 Predicate device.

Minor differences in the abutment designs and dimensions 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. The new abutment designs are supported by the K212108 Reference device and mechanical performance testing of worst-case constructs.

CONCLUSION

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

Overall, the Technological Characteristics of the Subject device are highly similar to the Predicate device.

The Subject device, the Predicate device, and the Reference devices have the same intended use, have similar technological characteristics, and are made of the same materials. The Subject device, the Predicate, and Reference devices encompass the same range of physical dimensions, are packaged in similar materials, and are to be sterilized using similar methods. The data included in this premarket notification demonstrate substantial equivalence to the Predicate device listed above.

Overall, the Sherlock Abutments Subject device is substantially equivalent to the Predicate device.

Comparison of Indications for Use Statement

Subject Device Sherlock Open Implants, LLC	Predicate Device Sherlock Open Implants, LLC K212664	Reference Device Sherlock Open Implants, LLC K193335	Reference Device Dynamic TiBase Talladium Espana K212108																																																																				
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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																																																		
Reason for Predicate/Reference	Not Applicable	Material, sterilization, biocompatibility, CAD/CAM abutment technology, implant compatibility	Material, sterilization, biocompatibility, CAD/CAM abutment technology, implant compatibility	CAD/CAM abutment technology, abutment design																																																		
Abutment Design	<p>Titanium Base Platform Diameter: 3.3 – 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 Post w/cut-out design for angulated screw channel</p> <p style="text-align: center;">CAD/CAM Design Parameters</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>IP**</th> <th>Min WT</th> <th>Min PH**</th> <th>GH</th> <th>PD</th> <th>CA</th> </tr> </thead> <tbody> <tr> <td>3.3-5.7</td> <td>0.5</td> <td>4.0, 5.0</td> <td>0.5-5.0</td> <td>4.4 -11.9</td> <td>0-30°</td> </tr> </tbody> </table> <p>* 0.5 mm minimum total GH (including mesostructure) * 5 mm maximum total GH (including mesostructure) **varies by implant line</p>	IP**	Min WT	Min PH**	GH	PD	CA	3.3-5.7	0.5	4.0, 5.0	0.5-5.0	4.4 -11.9	0-30°	<p>Titanium Blank Platform Diameter: 3.3 - 6.0 mm Minimum post height: 4.0 mm</p> <p style="text-align: center;">CAD/CAM Design Parameters</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>IP**</th> <th>Min WT**</th> <th>Min PH</th> <th>GH</th> <th>PD</th> <th>CA</th> </tr> </thead> <tbody> <tr> <td>3.3-6.0</td> <td>0.41-0.65</td> <td>4.0</td> <td>0.5-5.0</td> <td>3 -11.9</td> <td>0-30°</td> </tr> </tbody> </table> <p>**varies by implant line</p>	IP**	Min WT**	Min PH	GH	PD	CA	3.3-6.0	0.41-0.65	4.0	0.5-5.0	3 -11.9	0-30°	<p>Titanium Blank Platform Diameter: 3.5, 3.9 mm Minimum post height: 4.0 mm</p> <p style="text-align: center;">CAD/CAM Design Parameters</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>IP</th> <th>Min WT</th> <th>Min PH</th> <th>GH</th> <th>PD</th> <th>CA</th> </tr> </thead> <tbody> <tr> <td>3.5-3.9</td> <td>0.42</td> <td>4.0</td> <td>0.5-5.0</td> <td>3.4 -11.9</td> <td>0-30°</td> </tr> </tbody> </table>	IP	Min WT	Min PH	GH	PD	CA	3.5-3.9	0.42	4.0	0.5-5.0	3.4 -11.9	0-30°	<p>Titanium Base Platform Diameter: 3.5, 4.0, 4.5, 5.0 mm Minimum post height: 4.0 mm Gingival Height: 0.7 to 5 mm† Straight Ti-Base, no post angle. Post w/cut-out design for angulated screw channel</p> <p style="text-align: center;">CAD/CAM Design Parameters</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>IP</th> <th>Min WT</th> <th>Min PH</th> <th>Min GH</th> <th>Max GH</th> <th>PD</th> <th>CA</th> </tr> </thead> <tbody> <tr> <td>3.5-5.0</td> <td>0.43</td> <td>4.0</td> <td>0.7</td> <td>5.83</td> <td>n/s</td> <td>0-30°</td> </tr> </tbody> </table> <p>†Based on product labeling/literature</p>	IP	Min WT	Min PH	Min GH	Max GH	PD	CA	3.5-5.0	0.43	4.0	0.7	5.83	n/s	0-30°
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Abutment/Implant Interface	Internal connection, engaging and non-engaging	Internal connection, engaging	Internal connection, engaging	Internal connection, engaging and non-engaging																																																		
Prosthesis Attachment	Cement-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained																																																		
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit																																																		

IP = Implant Platform Diameter (mm) PH = Post Height (mm) PD = Prosthetic/Gingival Diameter (mm) n/s = not specified
WT = Wall thickness (mm) GH = Gingival Height (mm) CA = Post Correction angle (degrees)