November 30, 2021

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

Re: K212664
Trade/Device Name: Sherlock
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 29, 2021
Received: November 1, 2021

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

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)
Biomet 3i Certain	3.25	3.4
	4.0	4.1
	5.0	5.0
	6.0	6.0
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.

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510(k) Summary
Open Implants, LLC
Sherlock
K212664
November 30, 2021

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 design principles to the following predicate and reference devices:

510(k)	Predicate Device Name	Company Name
K193335	Sherlock	Open Implants, LLC

510(k)	Reference Device Name	Company Name
K101608	Encode® Patient Specific Dental Abutments	Biomet 3i, Inc
K150899	Straumann® CARES® Titanium Alloy (TAN) Abutment	Straumann USA, LLC
K143505	Zimmer® Patient Specific Abutment, Internal Hex, Titanium	Zimmer 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)
Biomet 3i Certain	3.25	3.4
	4.0	4.1
	5.0	5.0
	6.0	6.0
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

DEVICE DESCRIPTION

Sherlock is a dental implant abutment system that includes four (4) abutment designs compatible with three (3) OEM implant systems. The Subject device abutment platform diameters range from 3.0 mm to 6.5 mm, and the corresponding compatible implant body diameters also range from 3.0 mm to 6.5 mm. The subject device includes the following abutment designs: Titanium blank, multi-unit straight, multi-unit angled 17°, and multi-unit angled 30°. The system also includes corresponding abutment screws.

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 Blank	**Multi-unit Straight**	**Multi-Unit Angled 17°**	**Multi-Unit Angled 30°**	**Titanium Screws**
Biomet 3i Certain					
3.4 mm	**X**	**X**	**X**	**X**	**X**
4.1 mm	**X**	**X**	**X**	**X**	**X**
5.0 mm	**X**				**X**
6.0 mm	**X**				**X**
Straumann Bone Level					
3.3 mm (NC)	**X**	**X**	**X**	**X**	**X**
4.1 mm (RC)	**X**	**X**	**X**	**X**	**X**
4.8 mm (RC)	**X**	**X**	**X**	**X**	**X**
Zimmer TSV					
3.5 mm	**X**	**X**	**X**	**X**	**X**
4.5 mm	**X**	**X**	**X**	**X**	**X**
5.7 mm	**X**				**X**

All abutments and screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and are provided non-sterile to the end user. All digitally designed customized Titanium Blank abutments are to be sent to an Open Implants-validated milling center for manufacture.

The design parameters for the CAD/CAM Titanium Blank custom abutment are:

Minimum wall thickness – 0.41 to 1.6 mm (varies by implant line);

Minimum post height for single-unit restoration – 4.0 mm;

Maximum Correction Angle – 30°;
Minimum gingival height – 0.5 mm to 0.8 mm (varies by implant line);
Maximum gingival height – 5 mm.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: biocompatibility according to ANSI/AAMI ST72; biocompatibility testing of the K193335 Predicate device to ISO 10993-5 in support of the Subject device; reverse engineering of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility; and static compression and compression fatigue testing according to ISO 14801; sterilization validations of the K193335 Predicate device in support of the Subject device. For each compatible OEM implant line, worst-case constructs were subjected to static compression and compression fatigue testing. No animal or clinical 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 K193335 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. 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 and abutment designs to the sponsor's K193335 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 and restorative platform and implant diameters with similar intended uses.

The Subject device and K193335 Predicate devices are 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). The Subject device abutment designs are substantially equivalent to that of the K193335 Predicate device designs: Titanium Blank; Straight or Angled 17° and Angled 30° Multi-Unit abutments.

The Subject device includes abutment designs for implant restorative platforms ranging from 3.3 mm to 6.0 mm. The K193335 Predicate included implant platform sizes of 3.5 mm to 3.9 mm. Substantial equivalence of the smaller and larger implant restorative platform diameters of the Subject device are supported by the Reference devices K101608, K150899, and K143505 and through performance testing of the Subject device.

The Subject device is to be sterilized by the end-user, using the same methods as previously validated for the sponsor's K19335 Predicate device.

Minor differences in the designs, dimensions, sizes, or compatible OEM implant lines between the Subject device, the Predicate device, and the Reference devices do not affect substantial equivalence. Additional implant/abutment interfaces and dimensions are supported by Reference devices. The Subject, Predicate and Reference devices encompass the same range of physical dimensions. These minor differences are related to the compatible OEM implant designs and are mitigated by mechanical performance testing.

CONCLUSION

Overall, the Indications for Use statements for the Subject and Predicate devices are substantially equivalent 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 Predicate device with additional compatible implant systems supported by Reference devices.

Overall, the data included in this premarket notification demonstrate substantial equivalence of Subject device to the sponsor's Predicate device.

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

<table>
<tr>
<th>Subject Device
Sherlock
Open Implants, LLC</th>
<th>Predicate Device
Sherlock
Open Implants, LLC
K193335</th>
<th>Reference Device
Encode® Patient Specific Dental Abutments
Biomet 3i, Inc
K101608</th>
<th>Reference Device
Straumann® CARES® Titanium Alloy (TAN) Abutments
Straumann USA, LLC
K150899</th>
<th>Reference Device
Zimmer® Patient Specific Abutment, Internal Hex, Titanium
Zimmer Dental, Inc
K143505</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 rowspan="4">Biomet 3i Certain</td><td>3.25</td><td>3.4</td></tr>
<tr><td>4.0</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td>6.0</td><td>6.0</td></tr>
<tr><td>Straumann Bone Level</td><td>3.3</td><td>3.3 (NC)</td></tr>
<tr><td></td><td>4.1, 4.8</td><td>4.1, 4.8 (RC)</td></tr>
<tr><td rowspan="3">Zimmer TSV</td><td>3.7, 4.1</td><td>3.5</td></tr>
<tr><td>4.7</td><td>4.5</td></tr>
<tr><td>6.0</td><td>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>NobelActive®</td><td>3.5</td><td>3.5 (NP)</td></tr>
<tr><td></td><td>4.3, 5.0</td><td>3.9 (RP)</td></tr>
</table>
</td>
<td>BIOMET 3i Dental Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained to the abutment. Restorative Components:

• Temporary Healing Abutments are intended for use to shape and maintain the soft tissue opening during healing.

• Castable restorative components are intended for use as accessories to endosseous dental implants to aid in the fabrication of dental prosthetics.

• Screw components are intended for use as accessories to endosseous dental implants for retention of screw retained abutments to the dental implant.</td>
<td>The Straumann CARES® TAN abutments are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.</td>
<td>The Zimmer® Patient Specific Abutment is used as a terminal or intermediate abutment for a cemented prosthesis. The abutment can be used for a single or multiple-unit restoration.</td>
</tr>
</table>

Comparison of Indications for Use Statement

Comparison	**Subject Device** Sherlock Open Implants	**Predicate Device** Sherlock Open Implants, LLC K193335	**Reference Device** Encode®@ Patient Specific Dental Abutments Biomet 3i, Inc K101608	**Reference Device** Straumann® CARES® Titanium Alloy (TAN) Abutments Straumann USA, LLC K150899	**Reference Device** Zimmer® Patient Specific Abutment, Internal Hex, Titanium Zimmer Dental, Inc K143505
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
Reason for Predicate/Reference	Not Applicable	Abutment configurations listed, material, sterilization, biocompatibility, CAD/CAM abutment technology	Implant/abutment interface, prosthetic diameters, CAD/CAM abutment technology	Implant/abutment interface, prosthetic diameters, CAD/CAM abutment technology	Implant/abutment interface, prosthetic diameters, CAD/CAM abutment technology
	Titanium Blank Minimum wall thickness – 0.41 – 0.65 mm (varies by implant line); Minimum post height for single-unit restoration – 4.0 mm; Maximum Correction Angle – 30°; Gingival height – 0.5 to 5 mm; Gingival Diameter – 3.0 – 11.9 mm (varies by implant line) Abutment height – 6.4 - 15 mm (varies by implant line)	Titanium Blank Minimum wall thickness – 0.42 mm; Minimum post height for single-unit restoration – 4.0 mm; Maximum Correction Angle – 30°; Gingival Height – 0.5 mm to 5 mm; Gingival Diameter – 3.4 – 11.9 mm Abutment height – 7.3 - 15 mm	Abutment types, not specified, but consistent with Titanium Blank or Ti-Base/Hybrid abutment. Minimum wall thickness – not specified; Minimum post height for single unit restoration – not specified Maximum correction angle - 30°; Gingival Height - 0.25 minimum (3.4 mm internal connection) Gingival Diameter – 3.8 – 16 mm Abutment height – 4.75 - 15 mm	Titanium Blank / Stock Minimum wall thickness – 0.4 mm; Minimum post height for single unit restoration – not specified Maximum correction angle – NC - 0°, RC - 30°; Maximum gingival height – no limit; Gingival Diameter – not specified Abutment Height– not specified	Titanium Blank / Stock Minimum wall thickness – not specified; Minimum post height for single unit restoration – not specified Maximum correction angle - 30°; Maximum gingival height – no limit; Gingival Diameter: 3.5mm Platform: 3.5- 9.0 mm 4.5mm Platform: 4.5- 10.0 mm 5.7mm Platform: 5.7- 12.0 mm Abutment Height– not specified
	Multi-Unit Straight PD = 3.3 – 4.8 mm GH = 1, 1.5, 2, 2.5, 3, 3.5, 4, 5 mm GD = 4.8 mm PH = 4.4 mm (includes insert) AH = 7.4 - 12.5 mm (includes insert)	Multi-Unit Straight PD = 3.5, 3.9 mm GH = 1.5, 2, 3, 5 mm GD = 4.8 mm PH = 4.4 mm (includes insert) AH = 7.5 -11 mm (includes insert)			
	Multi-Unit 17° PD = 3.3 – 4.8 mm GH = 2, 2.5, 3, 3.5, 4 mm GD = 4.8 mm PH = 4.4 mm (includes insert) AH = 7.9 - 12.1 mm (includes insert)	Multi-Unit 17° PD = 3.5, 3.9 mm GH = 3.5, 5 mm GD = 4.8 mm PH = 4.4 mm (includes insert) AH = 7.3 – 10.8 mm (includes insert)			
	Multi-Unit 30° PD = 3.3 – 4.8 mm GH = 3, 3.5, 4, 4.5, 5 mm GD = 4.8 mm PH = 4.4 mm (includes insert) AH = 8.3 - 12.5 mm (includes insert)	Multi-Unit 30° PD = 3.5, 3.9 mm GH = 3.5, 5 mm GD = 4.8 mm PH = 4.4 mm (includes insert) AH = 7.7 – 11.2 mm (includes insert)			
Abutment/Implant Platform Diameter (mm)	3.3 - 6.0	3.5, 3.9	3.4, 4.1, 5.0, 6.0	3.3, 4.1, 4.8	3.5, 4.5, 5.7 mm
Material (Abutment and Screw)	Ti-6AL-4V Alloy	Ti-6AL-4V Alloy	Titanium Alloy or Biocompatible Zirconia TZP	Titanium Alloy (Ti-6AL-7NB)	Titanium 6Al-4V Alloy
Abutment/Implant Interface	Internal Connection	Internal Connection	Internal Connection and External Connection	Internal Connection	Internal Connection
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-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	Single-unit Multi-unit

Comparison of Technological Characteristics

PD = Abutment/Implant Platform (Restorative) Diameter
GH = Gingival Height
GD = Gingival Diameter
PH = Post Height
AH = Abutment Height