March 24, 2020

Open Implants, LLC
% Chris Brown
Manager
Aclivi, LLC
6455 Farley Road
Pinckney, Michigan 48169

Re: K193335
Trade/Device Name: Sherlock
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 18, 2019
Received: December 26, 2019

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193335

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)	Restorative Platform Diameter (mm)
NobelActive®	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)

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 – K193335
Open Implants, LLC
Sherlock
3/24/2020

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 Email:	Tamara Nazzal, Chief Growth Officer tnazzal@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
K183518	Preat Abutments	Preat Corporation

	Reference Device Name	
K121873	Avinent Implant System	Avinent Implant System, S.L.U.
K071370	NobelActive Internal Connection Implant	Nobel Biocare

DEVICE DESCRIPTION

Open Implants' Sherlock abutments are a system of dental implant abutments which have an implant /abutment interface design compatible with the OEM Nobel Biocare NobelActive implant system. Each Subject device implant abutment has a pre-manufactured implant connection interface. The implant body diameters are 3.5 mm with a restorative diameter of 3.5 mm (NP), 4.3 and 5.0 mm with a restorative diameter of 3.9 mm (RP).

The Subject device abutments, multi-unit sleeves and corresponding abutment screws are all pre-manufactured from Ti-6Al-4V ELI (Grade 23) titanium conforming to ASTM F136 and provided non-sterile to the user.

Subject device abutments are available in two configurations; a customizable titanium blank abutment, and a multi-unit abutment.

The titanium blank abutments are intended to be customized by means of CAD/CAM technology to provide basis or support for single or multiple tooth prosthetic restorations. All digitally designed customized abutments from titanium blank abutments are to be sent to an Open Implant-validated milling center for manufacture.

The Multi-unit abutments are intended to provide support for multiple tooth bridge supported prosthetic restorations. Multi-unit Temporary Cylinders are intended to be used to fabricate temporary multi-unit prosthetic restorations. The temporary cylinder and associated prosthetic restoration have a maximum intended use of six months.

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)	Restorative Platform Diameter (mm)
NobelActive®	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)

EQUIVALENCE TO MARKETED DEVICE

The Subject device is substantially equivalent to the predicate device with respect to Indications for Use and technological principles. The Comparison tables below compare the Indications for Use and Technological Characteristics of the Subject and Predicate devices.

Comparison of Indications for Use Statements

<table>
<tr><th>Device</th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device
Sherlock
Open Implants, LLC</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 System</th><th>Implant Body Diameter (mm)</th><th>Restorative 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></tr>
<tr><td>Predicate Device
Preat Abutments (K183518)
Preat Corporation</td><td>Preat 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. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture.

Compatible Implant Systems
<table><tr><th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr><tr><td>3i OSSEOTITE® Certain®</td><td>3.25</td><td>3.4</td></tr><tr><td></td><td>4.0</td><td>4.1</td></tr><tr><td></td><td>5.0</td><td>5.0</td></tr></table></td></tr>
</table>

Device	Indications for Use Statement		
		6.0	*6.0*
	Astra Tech OsseoSpeed™	*3.0*	*3.0*
		3.5, 4.0	*3.5, 4.0*
		4.5, 5.0	*4.5, 5.0*
	BioHorizons Tapered Internal	*3.0*	*3.0*
		3.5	*3.5*
		4.0	*4.5*
	HIOSSEN ET III	*3.5*	*Mini*
		4.0, 4.5, 5.0, 6.0, 7.0	*Regular*
	Implant Direct Legacy	*3.2*	*3.0*
		3.7, 4.2	*3.5*
		4.7, 5.2	*4.5*
		5.7, 7.0	*5.7*
	MegaGen AnyRidge	*3.5, 4.0, 4.5, 5.0, 5.5*	*3.5*
	Neoss	*3.5, 4.0, 4.5, 5.0, 5.5*	*4.1*
	NobelActive®	*3.5*	*NP*
		4.3, 5.0	*RP*
	Nobel Replace™	*3.5*	*NP*
		4.0, 4.3, 5.0	*RP*
		5.0	*WP*
		6.0	*6.0*
	Straumann® Bone Level	*3.3*	*NC*
		4.1, 4.8	*RC*
	Straumann® Tissue Level	*3.3, 4.1, 4.8*	*RN*
		4.8, 6.5	*WN*
	Zimmer Screw-Vent®/Tapered Screw-Vent®	*3.3, 3.7, 4.1*	*3.5*
		4.7	*4.5*
		6.0	*5.7*

The Subject device is only being offered in a configuration compatible with listed Nobel Active implant system while Predicate device is offered with more compatible platforms, but this does not change the intended use of the device to provide support for single-unit or multi-unit prosthetic restorations.

The Subject device is offered in titanium blank and multi-unit abutment configurations while the primary Predicate is offered in two-piece Ti-Base and one-piece titanium blank configurations. Language related to a Ti-base abutment is not included in the Indications for use of the Subject device. While the abutment configurations are different between the Subject and Predicate devices, this does not change the intended use of the devices to provide support for single-unit or multi-unit prosthetic restorations.

Slight differences in wording of the Indications for Use statements do not change the intended use of the Subject and Predicate devices to provide support for single or multi-unit prosthetic restorations.

Technological Characteristics Comparison Table

<table>
<tr><th>Parameter</th><th>Subject Device
Sherlock</th><th>Predicate Device
Preat Abutments
Preat Corporation
K183518</th><th>Reference Device
Avinent Implant System
Avinent Implant System, S.L.U.
K121873</th><th>Reference Device
NobelActive Internal Connection Implant
Nobel Biocare
K071370</th><th>Equivalence Discussion</th></tr>
<tr>
<td>Indications for Use</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 System</th><th>Implant Body Diameter (mm)</th><th>Restorative 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>Preat 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. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.
All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture.
Compatible Implant Systems
<table>
<tr><th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td>3i OSSEOTITE® Certain®</td><td>3.25</td><td>3.4</td></tr>
<tr><td></td><td>4.0</td><td>4.1</td></tr>
<tr><td></td><td>5.0</td><td>5.0</td></tr>
<tr><td></td><td>6.0</td><td>6.0</td></tr>
<tr><td>Astra Tech OsseoSpeed ™</td><td>3.0</td><td>3.0</td></tr>
<tr><td></td><td>3.5, 4.0</td><td>3.5, 4.0</td></tr>
<tr><td></td><td>4.5, 5.0</td><td>4.5, 5.0</td></tr>
<tr><td>BioHorizons Tapered Internal</td><td>3.0</td><td>3.0</td></tr>
<tr><td></td><td>3.5</td><td>3.5</td></tr>
<tr><td></td><td>4.0</td><td>4.5</td></tr>
<tr><td>HIOSSEN ET III</td><td>3.5</td><td>Mini</td></tr>
<tr><td></td><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular</td></tr>
<tr><td>Implant Direct Legacy</td><td>3.2</td><td>3.0</td></tr>
<tr><td></td><td>3.7, 4.2</td><td>3.5</td></tr>
<tr><td></td><td>4.7, 5.2</td><td>4.5</td></tr>
</table>
</td>
<td>The AVINENT dental implant system is for oral endosseous implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients.
AVINENT implants are for single-stage or two-stage surgical procedures and cement or screw retained restorations. Implants are intended for immediate loading on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function if the requirements in the surgical manual are satisfied.

Specific indications for small diameter (3.3 mm implants):

Because of their reduced mechanical stability, small diameter implants are only used in cases with a low mechanical load. Placement in maxillary incisors or mandibular central and lateral incisors.</td>
<td>Nobel Biocare's NobelActive implants are endosseous implant intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted on non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.</td>
<td>Substantially Equivalent
Differences in wording of Indications for Use statements do not change the intended use of the Subject, Predicate and Reference devices to provide support for single or multi-unit prosthetic restorations. Differences in restorative systems or platform diameters do not change the intended use of the Subject, Predicate and Reference devices to provide support for single or multi-unit prosthetic restorations. The fact that single abutment Subject and Predicate devices can be customized and Reference devices are not intended to be customized does not change the intended use of the Subject, Predicate and Reference devices to provide support for single or multi-unit prosthetic restorations.

The Subject device is offered in titanium blank and multi-unit abutment configurations while the primary Predicate is offered in two-piece Ti-Base and titanium blank configurations. Language related to a Ti-base abutment is not included in the Indications for use of the Subject device. While the abutment configurations are different between the Subject and Predicate devices, this does not change the intended use of the devices to provide support for single-unit or multi-unit prosthetic restorations. Additionally, the Avinent (K121873) Reference includes multi-unit abutments which supports a finding of substantial equivalence.</td>
</tr>
</table>

Parameter	**Subject Device** Sherlock	**Predicate Device** Preat Abutments Preat Corporation K183518	**Reference Device** Avinent Implant System Avinent Implant System, S.L.U. K121873	**Reference Device** NobelActive Internal Connection Implant Nobel Biocare K071370	**Equivalence Discussion**
		5.7, 7.0 / *5.7* *MegaGen AnyRidge* / *3.5, 4.0, 4.5, 5.0, 5.5* / *3.5* *Neoss* / *3.5, 4.0, 4.5, 5.0, 5.5* / *4.1* *NobelActive®* / *3.5* / *NP* *4.3, 5.0* / *RP* *Nobel Replace™* / *3.5* / *NP* *4.0, 4.3, 5.0* / *RP* *5.0* / *WP* *6.0* / *6.0* *Straumann® Bone Level* / *3.3* / *NC* *4.1, 4.8* / *RC* *Straumann® Tissue Level* / *3.3, 4.1, 4.8* / *RN* *4.8, 6.5* / *WN* *Zimmer Screw-Vent®/Tapered Screw-Vent®* / *3.3, 3.7, 4.1* / *3.5* *4.7* / *4.5* *6.0* / *5.7*			
Regulation #	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3640	21 CFR 872.3640	***Substantially Equivalent with Predicate***
Classification Name	Endosseous dental implant abutment	Endosseous dental implant abutment	Endosseous dental implant	Endosseous dental implant	***Substantially Equivalent with Predicate***
Product Code	NHA	NHA	DZE, NHA	DZE, NHA	***Substantially Equivalent with Predicate***
Classification	Class II	Class II	Class II	Class II	***Substantially Equivalent***
Materials	Titanium Ti-6Al-4V ELI (ASTM F136)	Titanium Ti-6Al-4V ELI (ASTM F136)	Abutments - Titanium Ti-6Al-4V ELI (ASTM F136) and PEEK	Abutments - Titanium Ti-6Al-4V ELI (ASTM F136)	***Substantially Equivalent with Predicate***
Surface Finish	Non-coated	Non-coated	Abutments – non-coated	Abutments – non-coated	***Substantially Equivalent with Predicate***
Abutment/ Implant Interface	Internal connection conical hex Multi-unit and temp abutments include non-engaging	Internal connection conical hex (for NobelActive Connection)	Internal hex and conical hex connections Multi-unit and temp abutments include non-engaging	Internal conical hex connection	***Substantially Equivalent*** *Multi-unit and temp non-engaging is Substantially equivalent with Reference Device*

Parameter	**Subject Device** Sherlock	**Predicate Device** Preat Abutments Preat Corporation K183518	**Reference Device** Avinent Implant System Avinent Implant System, S.L.U. K121873	**Reference Device** NobelActive Internal Connection Implant Nobel Biocare K071370	**Equivalence Discussion**
Abutment platform diameter	3.5 mm (NP for the NobelActive Connection) 3.9 mm (RP for the NobelActive Connection)	3.5 mm (NP for the NobelActive Connection) 3.9 mm (RP for the NobelActive Connection)	3.5 to 5.1 mm	3.5-3.9 (NP and RP)	***Substantially Equivalent*** *Predicate and reference device dimensions listed which are outside of the Nobel Active NP and RP connections are for other implant systems, not part of the Subject device submission and do not change the intended use of the devices. Any differences in dimensions have been validated through performance testing and support substantial equivalence.*
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement retained Screw-retained	Cement retained Screw-retained	***Substantially Equivalent***
Abutment Designs	Ti-Blank	Ti-Blank	Stock, fixed angulation 0°, 17°	Stock, fixed angulation 0°, 15°	***Substantially Equivalent*** *Differences in available abutment design configurations do not change the intended use of the devices. Subject and Predicate devices may be customized. Customizations have limitations which have been validated through performance testing and support substantial equivalence.*
	Multi-Unit Straight	Multi-Unit Straight	Multi-Unit Straight	Multi-Unit Straight	***Substantially Equivalent***
	Multi-Unit Angled 17°, 24°, 30°	Multi-Unit Angled 17°	Multi-Unit Angled 17°, 24°, 30°	Multi-Unit Angled 17°, 30°	***Substantially Equivalent*** *Multiple correction angle options of the Subject device not change the intended use of the device. Any differences in correction angles have been validated through performance testing and support substantial equivalence.*
Restoration	Single-unit & Multi-Unit	Single-unit & Multi-Unit	Single-unit & Multi-Unit	Single-unit & Multi-Unit	***Substantially Equivalent***
Mode of operation	Used in conjunction with endosseous dental implants to provide support for single and multi-unit prostheses.	Used in conjunction with endosseous dental implants to provide support for single and multi-unit prostheses.	Used in conjunction with endosseous dental implants to provide support for prosthetic reconstructions.	Used in conjunction with endosseous dental implants to provide support for single and multi-unit prostheses.	***Substantially Equivalent with Predicate*** *Slight differences in wording does not change that all devices are used to provide support for dental prosthesis.*
Sterility	Provided non-sterile	Provided non-sterile	Sterile	Sterile Multi-unit Non-sterile stock abutments.	***Substantially Equivalent with Predicate***
Sterilization method	Steam Sterilization	Steam sterilization	Gamma radiation	Not specified	***Substantially Equivalent with Predicate***
Abutment Design Parameters	Minimum wall thickness: 0.42 mm Maximum angulation: 30° Minimum post height: 4 mm Minimum gingival height: 0.5mm Maximum gingival height: 5 mm	Minimum wall thickness: 0.5 mm Maximum angulation: 30° (Ti-Blank) Minimum post height: 4 mm Maximum gingival height: 1.5 to 2.65mm (varies by implant line)	Minimum wall thickness: not specified Maximum angulation: 30° Minimum post height: not specified Minimum gingival height: 0.5mm	Minimum wall thickness: not specified Maximum angulation: 30° Minimum post height: not specified Minimum gingival height: 1.5 mm	***Substantially Equivalent*** *Slight differences in abutment design parameters do not change the intended use of the device. Differences in Subject Device specified parameters have been validated by fatigue testing a worst-case construct of the Subject device and support substantial equivalence.*

Parameter	**Subject Device** Sherlock	**Predicate Device** Preat Abutments Preat Corporation K183518	**Reference Device** Avinent Implant System Avinent Implant System, S.L.U. K121873	**Reference Device** NobelActive Internal Connection Implant Nobel Biocare K071370	**Equivalence Discussion**
			Maximum gingival height: 5 mm	Maximum gingival height: 4.5 mm	

The Subject and Predicate devices include Ti-Blank Abutments which can be customized by CAD/CAM technology. The Subject, Predicate and Reference devices all offer Straight or Angled Multi-Unit abutments. Customized Ti-Blank abutments, Multi-Unit abutments and "stock" or fixed angle abutments are all intended to provide support for the prosthetic devices.

Slight differences in available multi-unit abutment angles, maximum gingival height design parameters and platform diameters for the Subject, Predicate and Reference devices do not change the intended use of the devices to provide support for single and multi-unit prostheses. Offering fewer restorative platform diameters than the Predicate device does not change the intended use of the devices to provide support for single and multi-unit prostheses.

Overall, there may be slight differences in wording of Indications for Use or Mode of Operation statements, but the Subject, Predicate and Reference devices share a common intended use to provide support for prosthetic devices.

Overall, there may be slight differences between the Subject, Predicate and Reference devices in device design parameters, such as restorative implant system, platform diameters, abutment configurations, abutment correction angles, wall thicknesses, gingival heights, etc… Those differences don't change the intended use to provide support for prosthetic devices. Any differences in parameters, have been validated through performance testing and support a finding of Substantial Equivalence.

Overall, the Technological Characteristics of the Subject device are substantially equivalent to that of the Predicate and Reference devices.

NON-CLINICAL PERFORMANCE DATA

Non-clinical performance data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1 and ISO 14937; biocompatibility according to ISO 10993-5 and ANSI/AAMI ST72; reverse engineering of the OEM implant bodies, OEM implant abutments and OEM implant abutment screws to confirm compatibility; and fatigue testing according to ISO 14801. No clinical data is included in this submission.

CONCLUSION

Slight variations in the wording of the Indications for Use statements for the Subject and Predicate devices do not change the intended use of the devices to provide support for single or multi-unit prosthetic restorations.

Slight differences in the Technological Characteristics of the Subject and Predicate devices do not change the intended use of the devices to provide support for single or multi-unit prosthetic restorations. Differences in Subject device abutment design parameters were validated with respect to intended use through Performance testing, supporting a finding of substantial equivalence.

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