December 21, 2018

DIO Corporation
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

Re: K181037
Trade/Device Name: DIO CAD/CAM Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 19, 2018
Received: November 26, 2018

Dear April Lee:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181037

Device Name
DIO CAD/CAM Abutment

Indications for Use *(Describe)*

Indication for Use

DIO CAD/CAM Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)
UF(II) Narrow Implant System	3.0/ 3.3	3.0/ 3.3
UF Sub merged Implant System	3.8/4.0/4.5/5.0/5.5/6.0/6.5/7.0	3.8/4.0/4.5/5.0/5.5/6.0/6.5/7.0
UF(II) Implant System	3.8/4.0/4.5/5.0/5.5	3.8/4.0/4.5/5.0/5.5

Patient specific abutment is intended for use with the UF Implant Systems provided in the chart. All digitally designed abutments for use with DIO CAD/CAM Abutments are intended to be manufactured at a DIO Corporation validated milling center.

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

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Device Information

- Trade Name: DIO CAD/CAM Abutment
- Common Name: Endosseous dental implant abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II
- Date prepared: 12/21/2018

Predicate Devices:
The subject device is substantially equivalent to the following predicate device:

Primary Predicate
- Medentika CAD/CAM Abutment (K150203)

Reference Devices
- Sirona Dental CAD/CAM System (K111421)
- Zimmer® patient Specific Abutment, Internal Hex, Titanium(K143505)
- Encode Patient Specific Abutment for Straumann Bone Level Connection(K112730)
- UF(II) Narrow Implant System (K161987)
- UF Sub Merged Implant System (K122519)
- UF(II) Implant System (K170608)
- Self-Adhesive Resin Cement (K073173)
- ZIRMON SERIES (K131117)

Device Description

The DIO CAD/CAM Abutment includes two CAD/CAM abutment designs, Hybrid Link Abutment and Patient-Specific Abutment.

1) Hybrid Link abutment

Hybrid Link Abutment
Hybrid Link abutment is intended to provide support for customized prosthetic restorations such as crowns and bridges. The hybrid link abutment is composed of two-piece abutment that is a hybrid link at the bottom and a coping (CAD/CAM patient specific superstructure) at the top. The hybrid link abutments are pre-manufactured (stock) abutments, made from a titanium alloy conforming to ASTM F136. The diameters of Hybrid Link Abutment are 4.0/4.5/5.5mm.
Hybrid Link abutment is provided non-sterile therefore must be sterilized after the cementation of the patient-specific superstructure on the Hybrid Link Abutment.
The proposed devices are compatible with the following device.

Dental Implants

Proprietary Name	UF(II) Narrow Implant System	UF Sub merged Implant System	UF(II) Implant System
Compatible Implants (Knumber)	K161987	K122519	K170608
Implant diameter size	3.0/3.3	3.8/4.0/4.5/5.0/5.5/6.0/6.5 /7.0	3.8/4.0/4.5/5.0/5.5
Implant Interface Connection Type/Size(mm)	Internal connection type/2.3	Internal connection type/3.35	Internal connection type/3.35
Type of Implant-Abutment Connection	Hex/Non Hex	Hex/Non Hex	Hex/Non Hex

Raw material blanks

- K131117 ZIRMON SERIES manufactured by KUWOTECH CO., LTD

Raw material cement

- K073173 Self-Adhesive Resin Cement manufactureed by Densply is the cement

The coping that composes the final abutment should be designed and milled through the CAD/CAM software, according to the prosthetic planning and patient clinical situation. The coping and crowns designed using these or more recent versions of the CAD/CAM System, within the design limits as defined within the design software, are compatible with the Hybrid link abutment.
The coping would be manufactured by DIO Corporation only with design input using CAD/CAM Software from and by DIO Corporation milling center.

Design Limitation for Superstructure:

Super structure design Limitation (Unit: mm)			
Range (Diameter)	Range (Height)	Range (Wall thickness)	Range (Angle)

Min 4.0mm	Min 7.0mm	Min 0.5mm	0~15º

2) Patient-Specific Abutment

Patient-specific abutment is made from titanium alloy conforming to ASTM F136 titanium abutment to be used in fabricating patient-specific abutments. The subject abutments are indicated for cemented or "Screw-and Cement-Retained Prosthesis(SCRP)" restorations. Each patient-specific abutment is individually prescribed by the clinician.
The diameters of patient-specific Abutment are 3.0/3.3/3.8/4.0/4.5/5.0/5.5/6.0/6.5/7.0 and two connection designs (Hex, Non-hex).
Patient-Specific Abutment is compatible with following Implant Systems.

Proprietary Name	UF(II) Narrow Implant System	UF Sub merged Implant System	UF(II) Implant System
Compatible Implants (Knumber)	K161987	K122519	K170608
Implant diameter size	3.0/3.3	3.8/4.0/4.5/5.0/5.5/6.0 /6.5/7.0	3.8/4.0/45/5.0/5.5
Implant Interface Connection Type/Size(mm)	Internal connection type/2.3	Internal connection type/3.35	Internal connection type/3.35
Type of Implant-Abutment Connection	Hex/Non Hex	Hex/Non Hex	Hex/Non Hex

Patient-specific abutments are supplied with an abutment screw previous cleared device as K122519 and K161987 and provided non-sterile.

Patient-Specific Abutment design Limitation (Unit: mm)			
Model Name	Range (Diameter)	Range (Height)	Range (Angle)
CASSH CASSN	3.9~12.0	3.1~14.9	0~29.8º
CAUNH CAUNN	3.9~12.0	3.1~14.9	0~29.3º

Indication for Use

DIO CAD/CAM Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)
UF(II) Narrow Implant System	3.0/ 3.3	3.0/ 3.3
UF Sub merged Implant System	3.8/4.0/4.5/5.0/5.5/6.0/6.5/7.0	3.8/4.0/4.5/5.0/5.5/6.0/6.5/7.0
UF(II) Implant System	3.8/4.0/4.5/5.0/5.5	3.8/4.0/4.5/5.0/5.5

Patient specific abutment is intended for use with the UF Implant Systems provided in the chart. All digitally designed abutments for use with DIO CAD/CAM Abutments are intended to be manufactured at a DIO Corporation validated milling center.

Summaries of Technological Characteristics

The subject device is substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each individual diameter and connection type. Comparison demonstrating Substantial Equivalence follows:

1) Hybrid Link Abutment

	Subject Device	**Primary Predicate Device**	**Reference Device**
Applicant	DIO Corporation	Medentika GmbH	Sirona Dental Systems GmbH
Trade Name	DIO CAD/CAM Abutment	Medentika CAD/CAM Abutment	Sirona Dental CAD/CAM System TiBase Abutment
510(K) No.	K181037	K150203	K111421
Classification Name	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)
Product Code	NHA	NHA	NHA
Class	II	II	II
Material	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide	Titanium Alloy	Ti-6Al-4V ELI (ASTM F136) Zirconia Oxide
Design	Titanium Base	Titanium Base	Titanium Base
Diameters (mm)	4.0/4.5/5.5	3.25-7.0	3.5~6.5
Superstructure Angulation (°)	0~15	Up to 30	Up to 20
Superstructure material	Zirconia	Zirconia	Zirconia
Sterile	Steam Sterilization by user (Delivered non sterile)	Steam Sterilization by user (Provided Non-Sterile)	Steam Sterilization by user (Delivered non sterile)
Type of Retention	Screw-retained or cement retained	Cement-retained	Screw-retained or cement retained
Indications For Use	DIO CAD/CAM Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Implant System Compatibility: UF(II); Implant Diameter (mm): 3.0/ 3.3; Platform Diameter (mm): 3.0/ 3.3	Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Implant System Compatibility; Series; Implant Diameter (mm); Platform Diameter (mm)	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the titanium bases SSO 3.5L and SBL 3.3L, the indication is restricted for replacement of single lateral incisors in the maxilla and

	Narrow Implant System			Nobel Biocare Replace™ Select	E	3.5, 4.3, 5.0, 6.0	3.5, 4.3, 5.0, 6.0
	UF Sub merged Implant System	3.8/4.0/4.5/ 5.0/5.5/6.0/ 6.5/7.0	3.8/4.0/4.5/ 5.0/5.5/6.0/ 6.5/7.0	Nobel Biocare Nobel Active™	F	3.5, 4.3, 5.0	3.5, 3.9 (4.3), 3.9 (5.0)
	UF(II) Implant System	3.8/4.0/4.5/ 5.0/5.5	3.8/4.0/4.5/ 5.0/5.5	Biomet 3i Osseotite® Certain	H	3.25, 4.0, 5.0	3.4, 4.1, 5.0
				Biomet 3i Osseotite®	I	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
	Patient specific abutment is intended for use with the UF Implant Systems provided in the chart. All digitally designed abutments for use with DIO CAD/CAM Abutments are intended to be manufactured at a DIO Corporation validated milling center.			Nobel Biocare Branemark	K	3.3, 3.75, 4.0, 5.0	3.5, 4.1, 4.1, 5.1
				Straumann Bone Level	L	3.3, 4.1, 4.8	3.3, 4.1, 4.8
				Straumann Stnadard	N	3.3, 4.1, 4.8	3.5(NNC), 4.8, 6.5
				Zimmer Tapered Screw-vent®	R	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
				Austra Tech OsseoSpped™	S	3.5, 4.0, 4.5, 5.0	3.5, 4.0, 4.5, 5.0
				Dentsply Friadent® Frialit/XiVE®	T	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5
				Dentsply Friadent® Ankylos®	Y	3.5, 4.5, 5.5, 7.0	3.5, 4.5, 5.5, 7.0
				Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.			
	lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructured, and CAD/CAM software. Specifically, the inCoris mesostructured and TiBase components make up a two-piece abutment which is used in conjunction with endosseoous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructured may also be used in conjunction with the Camlog Titanium base CAD/CAM(types K2244.xxxx)(K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructured and TiBase two-piece abutment is compatible with the following implants systems: Nobel Biocare Replace(K020646) Nobel Biocare Branemark(K022562) Friadent Xive(K013867) Biomet 3i Osseotite(K980549) Astra Tech Osseospeed(K091239) Zimmer Tapered Screw-Vent(K061410) Straumann SynOcta(K061176) Straumann Bone Level(K053088, K062129, K060958) Biomet 3i Certain(K014235, K061629) Nobel Biocare Active(K071370)							
Substantial Equivalence Comparison	The subject Hybrid Link Abutment is substantially equivalent in designs, dimensions, material, indications, and technological characteristics with the identified primary predicate device. The DIO CAD/CAM Abutment is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special contr ols guidance document root-food endosseous dental implants and endosseous dental implant abutments. The diameters of the subject device are slightly different from the predicate devices. However, the subject diameters are in the range of diameters of predicates and this dimensional difference doesn't affect device safety and effectiveness. The Indications for Use of the subject and primary predicate device are identical other than the compatible implant bodies. This difference is mitigated by fatigue testing, reverse engineering, dimensional analysis, and identification of reference device for compatible implant bodies.							

	Both the predicate and subject devices are intended to be milled into patient specific abutments using CAD/CAM technology under the manufacturing control of the sponsor. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.

2) Patient-Specific Abutment

	Subject Device	**Primary Predicate Device**	**Reference Device**	
Applicant	DIO Corporation	Medentika GmbH	Zimmer Dental, Inc.	BIOMET 3i
Trade Name	DIO CAD/CAM Abutment	Medentika CAD/CAM Abutment	Zimmer® patient Specific Abutment, Internal Hex, Titanium	Encode Patient Specific Abutment for Straumann Bone Level Connection
510(K) No.	Not yet assigned	K150203	K143505	K112730
Classification Name	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)	Endosseous Dental Implant, Abutment (872.3630)
Product Code	NHA	NHA	NHA	NHA
Class	II	II	II	II
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Design	CAD/CAM Patient-Specific Abutment	CAD/CAM Blank	CAD/CAM Patient-Specific Abutment	CAD/CAM Patient-Specific Abutment
Diameters (mm)	CAD/CAM Patient-Specific Abutment : 3.0/3.3/3.8/4.0/4.5/5.0/5.5/6.0/6.5/7.0	3.0-7.0	3.5/ 4.5/ 5.7	3.3/ 4.1/ 4.8
Sterile	Steam Sterilization by user (Provided Non-Sterile)	Steam Sterilization by user (Provided Non-Sterile)	Steam Sterilization by user (Provided Non-Sterile)	Steam Sterilization by user (Provided Non-Sterile)
Type of Retention	Screw-retained or cement retained	Cement-retained	Screw-retained or cement retained	Screw-retained or cement retained
Abutment Seat	Sits on Taper	Sits on Taper	Sits on Taper	Sits on Taper
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity
Constructions	Machined	Machined	Machined	Machined
Indications For Use/ Intended Use	DIO CAD/CAM Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or	Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of	The Zimmer® Patient Specific Abutment is used as a terminal or	The 3i Patient-Specific Dental Abutment is intended for use as an

<table>
<tr>
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<td>mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>UF(II) Narrow Implant System</td><td>3.0/ 3.3</td><td>3.0/ 3.3</td></tr>
<tr><td>UF Sub merged Implant System</td><td>3.8/4.0/4.5/ 5.0/5.5/6.0/ 6.5/7.0</td><td>3.8/4.0/4.5/ 5.0/5.5/6.0/ 6.5/7.0</td></tr>
<tr><td>UF(II) Implant System</td><td>3.8/4.0/4.5/ 5.0/5.5</td><td>3.8/4.0/4.5/ 5.0/5.5</td></tr>
</table>
Patient specific abutment is intended for use with the UF implant systems provided in the chart. All digitally designed abutments for use with DIO CAD/CAM Abutments are intended to be manufactured at a DIO Corporation validated milling center.</td>
<td>a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare Nobel Active™</td><td>F</td><td>3.5, 4.3, 5.0</td><td>3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Certain</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Branemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Stnadard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Austra Tech OsseoSpped™</td><td>S</td><td>3.5, 4.0, 4.5, 5.0</td><td>3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
<tr><td>Dentsply Friadent® Ankylos®</td><td>Y</td><td>3.5, 4.5, 5.5, 7.0</td><td>3.5, 4.5, 5.5, 7.0</td></tr>
</table>
Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center.</td>
<td>intermediate abutment for a cemented prosthesis. The abutment can be used for a single of multiple-unit restoration.</td>
<td>accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.</td>
</tr>
<tr>
<td>Substantial Equivalence Comparison</td>
<td colspan="4">The subject Patient-Specific Abutment is substantially equivalent in designs, dimensions, material, indications, abutment seat, screw seat, anatomical site, connection, and technological characteristics with the identified primary predicate device. The DIO CAD/CAM Abutment is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA’s Class II special controls guidance document root-food endosseous dental implants and endosseous dental implant abutments.
Compared to the primary predicate device, the subject device different with predicate device design, the predicate device design is CAD/CAM Blank and the subject device is patient specific device. To support this discrepancy of different component inclusion, K143505 and K112730 were added as both predicates have the CAD/CAM patient specific abutment with equivalent design, dimensions, materials and indications.</td>
</tr>
</table>

	The Indications for Use of the subject and primary predicate device are identical other than the compatible implant bodies. This difference is mitigated by fatigue testing, reverse engineering, dimensional analysis, and identification of reference device for compatible implant bodies. Both the predicate and subject devices are intended to be milled into patient specific abutments using CAD/CAM technology under the manufacturing control of the sponsor. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.

Non-clinical Testing

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Fatigue Tests according to ISO 14801:2016
- End User Steam Sterilization Tests according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010
- Cytotoxicity testing according to ISO 10993-5:2009

Below tests were performed for predicate devices, K122519 and leveraged for the subject device:

- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Biocompatibility test data was used to evaluate the proposed device's substantial equivalence compared to the predicate device which is owned by the applicant. The results of the above tests have met the criteria of the standard and demonstrated the substantial equivalence with the predicate device.

Non-clinical testing was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", and it consisted of testing finished assembled implant/abutment systems of the worst-case scenario, (smallest diameter with maximum angulation) through fatigue testing.

Clinical testing was not necessary to establish substantial equivalency of the device.

Conclusion

The DIO CAD/CAM Abutment constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate device. Therefore, DIO CAD/CAM Abutment sand its predicates are substantially equivalent