August 9, 2018

Hager & Meisinger GmbH
Adam Tomczak
Regulatory Affairs
Hansemannstrasse 10
Neuss, 41468
GERMANY

Re: K173819
Trade/Device Name: MyPlant II Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 2, 2018
Received: July 9, 2018

Dear Adam Tomczak:

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)*
K173819

Device Name
MyPlant II Implant System

Indications for Use *(Describe)*
The MyPlant II implants are surgically placed in the maxilla or mandible to enable prosthetic restorations in edentulous or partially edentulous patients. The implants are to be used exclusively with MyPlant II abutments and prosthetic components. The abutments serve for prosthetic restorations and can include individual crowns, bridges, partial or full prostheses. Abutments can be used for single tooth restorations or for the restoration of several teeth. The implants are intended for delayed loading with two surgical interventions. In case of appropriate primary stability (35 Ncm), immediate temporary restoration with appropriate occlusal load can also be performed.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Traditional
MyPlant II Implant System
Section #5
510(k) Summary

1. Applicant's Name and Address:

Hager & Meisinger GmbH
Hansemannstrasse 10
41468 Neuss
Germany
Phone: 0049 2131 2012 293
Fax: 0049 2131 2012 223
Contact Person: Dr. Adam Tomczak, Regulatory Affairs

2. Date prepared:

Date prepared: 9 August 2018

3. Name of the Device:

Trade Name:	MyPlant II Implant System
Common Name:	Dental Implants, Dental Implant Abutments
Classification Name:	Root-form Endosseous Dental Implants, Endosseus Dental Implant Abutment Devices
Product Code:	DZE
Subsequent Product Code:	NHA
Regulation No:	872.3640
Class:	II
Panel:	Dental

4. Primary Predicate Device:

510(k) No.	Manufacturer	Trade Name
K143539	Hager & Meisinger GmbH.	Dental Implant System OKTAGON® Bone Level

Reference Devices:

510(k) No.	Manufacturer	Trade Name
K083805	Dentsply International, Inc	ANKYLOS® C/X Dental Implant System
K132214	Hager & Meisinger GmbH	Dental Implant Abutment OKTAGON®
K172505	MIS Implants Technologies Ltd	MIS C1 Narrow Platform Conical Connection Implant System MIS C1 Wide Platform Conical Connection Abutments

510(k) Traditional
MyPlant II Implant System
Section #5
510(k) Summary

5. Device Description:

Implants

The MyPlant II implant system serves as a tooth root substitute and can be used in free jaw sections or edentulous jaws. The MyPlant II implant is made of pure titanium Grade 4 (3.7065). The implant surface is micro-structured. The surface structure is created by blasting with white corundum (> 99 % Al_2O_3 = aluminum oxide) and etching with acid. Prosthetic connection and thus force transmission is conveyed via an internal cone. A sterile cover screw of 1 mm height is enclosed with each implant to enable an immediate occlusion of the internal thread after successful insertion. The implants are supplied sterile and are intended for single use. MyPlant II Implant System includes the following implant variations:

Article No.	Diameter [mm]	Length [mm]
A3580	3.5	8.0
A3595	3.5	9.5
A3511	3.5	11.0
A3514	3.5	14.0
M4080	4.0	8.0
M4095	4.0	9.5
M4011	4.0	11.0
M4014	4.0	14.0
B4580	4.5	8.0
B4595	4.5	9.5
B4511	4.5	11.0
B4514	4.5	14.0

Abutments

Dental abutments are used to support prosthetic reconstruction. Prosthetic applications can include individual crowns, bridges, partial or full prostheses. Abutments can be used for the replacement of one or more teeth. Depending on the indication and the anatomical conditions, the user will use several components for the specific prosthetic purpose. All components are made of a material suitable for the purpose of the application. The abutments are made of pure titanium Grade 4 (3.7065), titanium alloy Grade 5-ELI (Grade 23/3.7165), or PEEK. Except for the PEEK healing caps, the abutment surface is anodized. Connection to the implant is assured via an internal tapered

connection as well as a metric thread. In the case of Abutments 0°/15° and Shoulder Abutments, the abutment screw is not anodized and undergoes laser welding to connect the threaded sleeves with the shaft. The subject abutments are listed in the table below.

Article No.	**Description**	**Specifications [mm]** GH=gingiva height, H=height, L=length
PAB01	Abutment 0°	GH 1.5 H 4.0
PAB02	Abutment 0°	GH 1.5 H 6.0
PAB03	Abutment 0°	GH 3.0 H 4.0
PAB04	Abutment 0°	GH 3.0 H 6.0
PAB51	Abutment 15°	GH 1.5 H 4.0
PAB52	Abutment 15°	GH 1.5 H 6.0
PAB53	Abutment 15°	GH 3.0 H 4.0
PAB54	Abutment 15°	GH 3.0 H 6.0
PSA01	Shoulder Abutment 0°	GH 1.5 H 6.0
PSA02	Shoulder Abutment 0°	GH 3.0 H 6.0
PSA51	Shoulder Abutment 15°	GH 1.5 H 6.0
PSA52	Shoulder Abutment 15°	GH 3.0 H 6.0
PKA01	Ball Anchor	GH 1.5
PKA02	Ball Anchor	GH 3.0
PKA03	Ball Anchor	GH 4.5
PGF15	Healing Abutment	GH 1.5
PGF30	Healing Abutment	GH 3.0
PGF45	Healing Abutment	GH 4.5
PHK01	Healing Cap	H 4.0
PHK02	Healing Cap	H 6.0
PVS00	Cover Screw 0 mm	L 5.5
PVS01	Cover Screw 1 mm	L 6.5

Article No.	Description	Specifications [mm] GH=gingiva height, H=height, L=length
PVS02	Cover Screw 2 mm	L 7.5
POS01	Occlusal Screw	L 4.5
PSVK1	Screw for Ceramics	L 4.5

6. Indications for Use:

The MyPlant II implants are surgically placed in the maxilla or mandible to enable prosthetic restorations in edentulous or partially edentulous patients. The implants are to be used exclusively with MyPlant II abutments and prosthetic components. The abutments serve for prosthetic restorations and can include individual crowns, bridges, partial or full prostheses. Abutments can be used for single tooth restorations or for the restoration of several teeth. The implants are intended for delayed loading with two surgical interventions. In case of appropriate primary stability (35 Ncm), immediate temporary restoration with appropriate occlusal load can also be performed.

7. Basis for substantial equivalence

The tables below compare the Indications for Use Statements and the technological characteristics of the subject device system and the predicate/reference devices.

Comparison of Indications for Use Statements:

	Indications for Use Statement
Subject Device	
K173819 MyPlant II Implant System	The MyPlant II implants are surgically placed in the maxilla or mandible to enable prosthetic restorations in edentulous or partially edentulous patients. The implants are to be used exclusively with MyPlant II abutments and prosthetic components. The abutments serve for prosthetic restorations and can include individual crowns, bridges, partial or full prostheses. Abutments can be used for single tooth restorations or for the restoration of several teeth. The implants are intended for delayed loading with two surgical interventions. In case of appropriate primary stability (35 Ncm), immediate temporary restoration with appropriate occlusal load can also be performed.
Primary Predicate	
K143539 Dental Implant System	The implants are surgically placed in the maxillary and/ or mandibular arches to provide support for prosthetic restorations in edentulous or

OKTAGON® Bone Level	partially edentulous patients. The implants are intended to be used with OKTAGON® Bone Level abutments and prosthetic parts. Dental Implant Abutments Bone Level are intended to provide support for prosthetic reconstructions. Prosthetic applications can include individual crowns, bridges, partial or total prostheses. Abutments can be used in single tooth replacements and multiple tooth restorations. The Abutments are intended to be compatible to OKTAGON® Bone Level implants with diameters 3.3mm, 4.1mm and 4.8mm and with the lengths 8mm, 10mm, 12mm and 14mm. The Oktagon Bone Level System is intended for delayed loading, or for immediate loading when good primary stability is achieved and with appropriate occlusal load.
Reference Devices	
K083805 ANKYLOS® C/X Dental Implant System	The ANKYLOS® C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.
K132214 Dental Implant Abutment OKTAGON®	Dental Implant Abutments are intended to provide support for prosthetic reconstructions. Prosthetic applications can include individual crowns, bridges, partial or total prostheses. Abutments can be used in single tooth replacements and multiple tooth restorations. The Dental Implant Abutments OKTAGON® are intended to be compatible to OKTAGON® implants (Dental Implant OKTAGON®) with diameters 3.3mm, 4.1mm and 4.8mm in the variation Regular Platform, Wide Platform and Tapered Design with the lengths 8mm, 10mm, 12mm and 14mm.
K172505 MIS C1 Narrow Platform Conical Connection Implant System MIS C1 Wide Platform Conical Connection Abutments	MIS dental implant system is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.

The comparison of Indications for Use Statements shows that the subject device and the primary predicate have the same intended use. Both implant systems are surgically placed in the maxilla or the

mandible to provide support for single tooth or multiple tooth restorations. The surgical procedure may be two-stage or single-stage, with the possibility of immediate prosthetic restoration with appropriate occlusal load (in case of good primary stability). K143539 Indications for Use Statement additionally states that "The Abutments are intended to be compatible to OKTAGON® Bone Level implants with diameters 3.3mm, 4.1mm and 4.8mm and with the lengths 8mm, 10mm, 12mm and 14mm". This information about implant-abutment compatibility does not change the intended use. Further small differences in wording do not change the intended use.

Comparison of technological characteristics - implants:

	MyPlant II Implant System (subject device)	Dental Implant System OKTAGON® Bone Level (primary predicate)	ANKYLOS® C/X Dental Implant System (reference device)	MIS C1 Narrow Platform Conical Connection Implant System MIS C1 Wide Platform Conical Connection Abutments (reference device)
510(k) No.	K173819	K143539	K083805	K172505
Implant Type	Bone-level	Bone-level	Bone-level	Bone-level
Material	Titanium Grade 4	Titanium Grade 4	Titanium Grade 2	Ti6Al4V Grade 5-ELI
Endosseous Surface	Micro-structured (grit blasted and acid-etched)	Micro-structured (grit blasted and acid-etched)	Micro-structured (grit blasted and acid-etched)	Micro-structured (grit blasted and acid-etched)
Thread Design	Progressive	Consistent	Progressive	Progressive
Implant-abutment connection	Tapered, without indexation	Octagonal	Tapered, available with and without indexation	Tapered, with indexation
Implant Length	8.0 / 9.5 / 11.0 / 14.0 mm	8.0 / 10.0 / 12.0 / 14.0 mm	8.0 / 9.5 / 11.0 / 14.0 / 17.0 mm	10.0 / 11.5 / 13.0 / 16.0 mm

Endosseous Diameter	3.5 / 4.0 / 4.5 mm	3.3 / 4.1 / 4.8 mm	3.5 / 4.5 / 5.5 / 6.5 mm	3.3 mm
Sterility	Provided sterile; irradiation	Provided sterile; irradiation	Provided sterile; irradiation	Provided sterile; irradiation

As compared to the primary predicate K143539, the subject implants use the same materials and manufacturing methods. With regard to length and diameter, the subject implants lie within the range of the predicate device. The sterilization method is the same. However, the thread design and the implant-abutment connection are different. This gap is closed by K083805 implants, which have the same thread design and implant-abutment connection type (self-locking inner cone + retention screw). The main design difference between the subject device system and K083805 reference device is the extension of the inner cone connection which provides the implant-abutment interface. The effects of this design change have been evaluated by fatigue testing and FEM analysis, supporting substantial equivalence.

Comparison of technological characteristics abutments:

	MyPlant II Implant System (subject device)	Dental Implant System OKTAGON® Bone Level (primary predicate)	ANKYLOS® C/X Dental Implant System (reference device)	Dental Implant Abutment OKTAGON® (reference device)	MIS C1 Narrow Platform Conical Connection Implant System MIS C1 Wide Platform Conical Connection Abutments (reference device)
510(k) No.	K173819	K143539	K083805	K132214	K172505
Material	Ti6Al4V Gr.5 – ELI Titanium Gr. 4 PEEK	Ti6Al4V Gr.5 – ELI Titanium Gr. 4 POM-C	Ti6Al4V POM	Ti6Al4V Gr.5 – ELI Titanium Gr. 4 POM-C	Ti6Al4V - ELI PEEK POM Gold alloy
Angulation	0° / 15°	0°	0° - 22.5°	0° - 20°	0° - 30°
Implant-abutment connection	Tapered, without indexation	Octagonal	Tapered, available with and without indexation	Octagonal	Tapered, with indexation
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile

510(k) Traditional
MyPlant II Implant System
Section #5
510(k) Summary

The subject abutments are intended to enable various single-tooth and multiple tooth restorations. With respect to the predicate, the main differences are the angulation (the predicate does not include angled abutments), and the implant-abutment connection. This gap is bridged by K083805 abutments, which are very similar to the subject abutments in terms of design. Below the intended use and the technological characteristics have been compared with predicate/reference device for each abutment type included in this submission, and the most similar predicate/reference abutment has been identified. Regarding indexation of the implant-abutment connection, the reference device K083805 allows the user to choose between indexed (/X) and unindexed connection (/C). The subject device system will be made available without indexation, so substantial equivalence to the /C variation is claimed.

Abutments 0° / 15° (PAB01-04, PAB52-54)

	MyPlant II Implant System (subject device)	ANKYLOS® C/X Implant System (reference device)	ANKYLOS® C/X Implant System (reference device)
K Number	K173819	K083805	K083805
Product Name	Abutments 0° / 15°	Standard C/Abutments	SynCone C/ Abutments
Intended Use	Support screw-retained restorations or overdentures on prefabricated taper caps	Support cemented or screw-retained restorations	Support overdentures on prefabricated taper caps
Material	Ti6Al4V Gr.5 - ELI	Ti6Al4V	Ti6Al4V
Diameter	3.5 mm	3.3 / 4.5 mm	4.0 mm
Gingiva height	1.5 / 3.0 mm	1.5 / 3.0 / 4.5 / 6.0 mm	1.5 / 3.0 / 4.5 mm
Post height	4.0 / 6.0 mm	4.0 / 6.0 mm	4.0 mm
Angulation	0° / 15°	0° / 15°	0° / 15° / 22.5°
Connection to implant	Tapered + metric thread, without indexation	Tapered + metric thread, without indexation	Tapered + metric thread, without indexation
Sterility	Non-sterile	Non-sterile	Non-sterile

The subject abutments are substantially equivalent to the reference device in all features. There is a small difference in the abutment diameter, but the subject device lies within the range of the predicate. The SynCone C/ Abutment has been included in the comparison because, as in the case of

the subject abutment, the abutment body is tapered to enable prosthetic restoration with overdentures on taper caps (this form of restoration is not possible on K083805 Standard C/ abutment).

Shoulder Abutments (PSA01-02, PSA51-52)

	MyPlant II Implant System (subject device)	ANKYLOS® C/X Implant System (reference device)
K Number	K173819	K083805
Product Name	Shoulder abutments	Regular C/Abutments
Intended Use	Support cemented or screw-retained restorations	Support cemented or screw-retained restorations
Material	Ti6Al4V Gr.5 - ELI	Ti6Al4V
Diameter	5.0 mm	5.7 mm
Gingiva height	1.5 / 3.0 mm	0.75 / 1.5 / 3.0 / 4.5 mm
Post height	6.0 mm	6.6 / 7.0mm
Angulation	0°/15°	0°/ 15°/ 22.5°
Connection to implant	Tapered + metric thread, without indexation	Tapered + metric thread, without indexation
Sterility	Non-sterile	Non-sterile

The subject shoulder abutments are substantially equivalent to the reference device in all features despite small differences in dimensions. In the subject device, the post height is shorter, and the abutment diameter is slightly narrower. However, these differences do not represent a new worst-case within this submission.

Ball Anchors (PKA01-03)

	MyPlant II Implant System (subject device)	ANKYLOS® C/X Implant System (reference device)	Dental Implant Abutment OKTAGON® (reference device)
K Number	K173819	K083805	K132214

510(k) Traditional
MyPlant II Implant System
Section #5
510(k) Summary

Product Name	Ball Anchor	Snap Attachment C/	Retentive Anchor
Intended Use	Support retentively-fixated overdentures	Support retentively-fixated overdentures	Support retentively-fixated overdentures
Material	Titanium Grade 4	Ti6Al4V	Titanium Grade 4
Diameter (snap attachment sphere)	2.25 mm	2.7 mm	2.25 mm
Gingiva height	1.5 / 3.0 /4.5 mm	1.5 / 3.0 /4.5 mm	Non-applicable (to be used with a tissue-level implant)
Height	3.5 mm	3.5 mm	3.4 mm
Angulation	Straight	Straight	Straigth
Connection to implant	Tapered + metric thread, without indexation	Tapered + metric thread, without indexation	Octagonal
Sterility	Non-sterile	Non-sterile	Non-sterile

The subject ball anchors are substantially equivalent to the reference devices in almost all features. In the subject device the snap sphere is narrower. This gap is closed by the reference device K132214, which uses an attachment sphere of the same size.

Healing abutments (PGF15, PGF30, PGF45)

	MyPlant II Implant System (subject device)	ANKYLOS® C/X Implant System (reference device)
K Number	K173819	K083805
Product Name	Healing abutment	Standard C/ Sulcus Former
Intended Use	Closing the implant and shaping of the peri-implant soft tissue during transgingival healing	Closing the implant and shaping of the peri-implant soft tissue during transgingival healing
Material	Titanium Grade 4	Ti6Al4V
Diameter	Compatible with planned abutment of 3.5 mm diameter	Compatible with planned abutment of 3.3 / 4.5 mm diameter

Height	Non-applicable	Non-applicable
Gingiva height	1.5 / 3.0 / 4.5 mm	1.5 / 3.0 / 4.5 / 6.0 mm
Angulation	Straight	Straight
Connection to implant	Tapered + metric thread, without indexation	Tapered + metric thread, without indexation
Sterility	Non-sterile	Non-sterile

The subject healing abutments are substantially equivalent to the reference device in all features. There is a minimal difference in the planned abutment diameter, but the subject device lies within the range of the predicate.

Healing caps (PHK01-02)

	MyPlant II Implant System (subject device)	ANKYLOS® C/X Implant System (reference device)	MIS C1 Narrow Platform Conical Connection Implant System MIS C1 Wide Platform Conical Connection Abutments (reference device)
K Number	K173819	K080385	K172505
Product Name	Healing Caps	Standard Temporary Cap	Plastic Healing Caps
Intended Use	Cover the abutment and provide interface for temporary restoration	Cover the abutment and provide interface for temporary restoration	Cover the abutment until permanent restoration is ready
Material	PEEK	POM	PEEK
Diameter	3.5 mm	3.3 / 4.5 mm	No public data available
Height	4.0 / 6.0 mm	4.0 / 6.0 mm	4.0 / 6.0 / 8.0 mm
Gingiva height	-	-	-
Angulation	-	-	-
Connection to Implant	Non-applicable (the healing cap is mounted on the	Non-applicable (the healing cap is mounted on the	Non-applicable (the healing cap is mounted on the

	abutment)	abutment)	abutment)
Sterility	Non-sterile	Non-sterile	Non-sterile

The subject healing caps are substantially equivalent to the reference devices in almost all features. The subject device uses a different material. This gap is closed by the reference device K172505, which includes a healing cap made of the same material.

Cover Screws (PVS00-02)

	MyPlant II Implant System (subject device)	ANKYLOS® C/X Implant System (reference device)
K Number	K173819	K083805
Product Name	Cover Screw	C/X Cover Screw
Intended Use	Closing the implant during subgingival healing	Closing the implant during subgingival healing
Material	Titanium Grade 4	Ti6Al4V
Diameter	2.7 / 3.0 / 3.5 mm	2.5 - 3.5 mm
Height (above implant shoulder)	0.0 / 1.0 / 2.0 mm	0.0 / 1.0 / 2.0 mm
Gingiva height	Non-applicable	Non-applicable
Angulation	Non-applicable	Non-applicable
Connection to implant	Tapered + metric thread, without indexation	Tapered + metric thread, without indexation
Sterility	Sterile when delivered in the implant package; Non-sterile as spare part	Sterile when delivered in the implant package; Non-sterile as spare part

The subject cover screws are substantially equivalent to the reference device in all features.

Occlusal Screw (POS01), Screw for Ceramics (PVSK01)

	MyPlant II Implant System	ANKYLOS® C/X Implant

	(subject device)	System (reference device)
K Number	K173819	K083805
Product Name	Occlusal Screw, Screw for Ceramics	Fixation screw
Intended Use	Fixation of screw-retained restorations	Fixation of screw-retained restorations
Material	Ti6Al4V Gr. 5 -ELI	Ti6Al4V
Thread acc. to ISO 1502	M2	M1.4 / M1.6
Height	Non-applicable	Non-applicable
Gingiva height	Non-applicable	Non-applicable
Angulation	Non-applicable	Non-applicable
Connection to implant	Non-applicable	Non-applicable
Sterility	Non-sterile	Non-sterile

The subject screws for screw-retained restorations are substantially equivalent to the reference device in all features. There is a small difference in the thread size, but using a slightly larger thread for screw-retained restorations does not raise new performance or safety issues.

In summary, the above comparison shows that the subject abutments are substantially equivalent to the legally marketed predicate/reference devices. The intended use is identical, the used materials are the same or very similar, and the design parameters fall into the range of predicate/reference devices. Except for the healing caps made of PEEK, the manufacturing methods are shared with the predicate device K143539, albeit with a difference in the manufacturing process of the abutment screw used for Abutments 0° / 15° (PAB01-04, PAB52-54) and Shoulder Abutments (PSA01-02, PSA51-52). K143539 screws are manufactured as one part and are anodized, whereas the proposed screws use laser welding to connect the threaded sleeve with the shaft and are not anodized.

8. Performance tests and used standards

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include:

• Gamma sterilization validation according to ISO 11137-1 and 11137-2 (conducted on the subject device).

• Steam sterilization validation according to ISO 17665 and ST79 (referenced from K132214).

• Cleaning validation: LAL endotoxin test according to USP [85] and ANSI AAMI ST72 (referenced from K132214).

• Sterile barrier system validation according to ISO 11607, ASTM F88/F88M-15 and ASTM F1929-15 (conducted on the subject device).

• Biocompatibility assessment according to ISO 10993-1 and cytotoxicity testing according to ISO 10993-5 (proposed implants: referenced from K143539, proposed abutments: conducted on the subject device).

• Fatigue testing according to ISO 14801 and FDA Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments (conducted on the subject device).

No animal testing or human clinical trials have been conducted.

9. Conclusion

The subject device and the legally marketed predicate device have identical intended use. The technological characteristics are the same or very similar, as shown by the predicate/reference device comparison. Based on the assessment of applicable performance data, the subject device system does not raise new performance or safety issues. Thus, we concluded that the subject device is substantially equivalent to the legally marketed predicate device listed above.