March 11, 2019

Medical Instinct Deutschland GmbH
% Andre Weingerl
RA Consultant
WRC Consulting
Am Hohsetter 1A
Steislingen 78256
GERMANY

Re: K182313
Trade/Device Name: BoneTrust® Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 6, 2019
Received: February 13, 2019

Dear Andre Weingerl:

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)*
K182313

Device Name
BoneTrust® Implant System

Indications for Use *(Describe)*
BoneTrust® Dental Implants are medical devices intended to be surgically placed in the bone of the maxillary and/or mandibular arches to provide support for prosthetic restorations (crowns, bridges or overdenture) in edentulous or partially edentulous patients to restore a patients' chewing function.

BoneTrust® implants can also be used for immediate loading when sufficient primary stability is achieved and with appropriate occlusal loading.

BoneTrust® Short Dental Implants with length 6.5 mm are intended for delayed loading only

BoneTrust® Abutments and Prosthetic parts are intended for use with Bone Trust Dental Implants in the maxillary and/or mandibular arches to provide support for crowns, bridges or overdenture for edentulous or partially edentulous patients.

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."

K182313

510(k) Summary

Date Prepared: 2019-03-09

APPLICANT: Medical Instinct Deutschland GmbH
Graseweg 24
37120 Bovenden
Germany
Tel.: +49 5593 95196
Fax.: +49 5593 95195

E-Mail: info@medical-instinct.de
Internet: www.medical-instinct.de

CONTACT PERSON: Jan Worlitz
Managing Director
Tel.: +49 5593 95196
E-Mail: worlitz@medical-instinct.de

1. Device Name

Trade Names: BoneTrust® Implant System
Classification Name: Endosseous dental implant

2. Classification Product Code / Subsequent Code

BoneTrust® Implant System can be classified according to following Device Name and Product Code:

Product Code: DZE

Device Class: 2

Classification Panel: Dental

Regulation number: 21 CFR 872.3640

Secondary Product Code: NHA

3. Predicate device

- **Primary Predicate Device**

Straumann Dental Implant System; Stramann USA, LLC #K150938

- **Reference Devices**

CAMLOG Abutments; Altatec GmbH	#K083496
Nobelactive Multi Unit Abutments; Nobel Biocare AB	#K072570
Straumann RN synOcta UCLA Gold Abutment; Institut Straumann AG	#K041295
Conelog Implant System; Altatec GmbH	#K113779
STRAUMANN HEALING ABUTMENTS, HEALING CAPS, CLOSURE SCREWS	#K130808
SIC Invent Dental Implant Systems; SIC Invent AG	#K173207
BIOMET 3i Dental Abutments	#K072642
XIVE@ Dental Implant System	#K021318
Healing Cap Multi-Unit Titanium, Nobel Biocare AB	#K171142

4. Device Description

The BoneTrust® Implant System includes various sizes of threaded root-form dental implants and abutments intended to support prosthetic restorations in edentulous or partially edentulous patients.

4.1. Implants

The BoneTrust® Implants are bone level, root form implants constructed of commercially pure titanium (Grade 4) per ISO 5832-2, with a sand-blasted, acid-etched surface treatment. BoneTrust® Implants are screw- shaped dental implants with a Hexagon or conical torx internal connection.

Bone Trust Implants are provided in the following specifications:

Representative Picture	Specification	Value
	Sizes - Diameter x length (mm)	3.4 x 8.0 / 3.4 x 10.0 / 3.4 x 11.5 / 3.4 x 13.0 / 3.4 x 14.5 4.0 x 6.5 / 4.0 x 8.0 / 4.0 x 10.0 / 4.0 x 11.5 / 4.0 x 13.0 / 4.0 x 14.5 5.0 x 6.5 / 5.0 x 8.0 / 5.0 x 10.0 / 5.0 x 11.5 / 5.0 x 13.0
	Design	Conical screw implant Self-tapping screw design Integrated “platform switching” Internal connection hexagonal / internal connection with conical torx socket
	Material	Titan Grade 4 (ISO 5832-2:1999 / ASTM F67-06:2006)
	Surface	Micro-structured blasted etched surface passivated
	Packaging / Sterilization	Sterile packed in blister; Sterilized by beta irradiation

4.2. Abutments

BoneTrust® Dental Abutments are intended for cement-retained and screw-retained restorations. A cylindrical internal hexagon or conical torx allows connection to the BoneTrust® implant. BoneTrust® Dental Abutments are available in different designs

4.2.1. Esthetic Abutments

BoneTrust® Esthetic and Wide Body Abutments are premanufactured single-piece abutments constructed of titanium alloy per ISO 5832-3 and intended to be used for cemented single-tooth and bridge restorations as well as temporary single tooth restorations. BoneTrust® Esthetic Abutments are available in the following shapes:

Esthetic Abutments			
	Available sizes	Platform Diameter	Sizes (Angulation, Gingival Height (GH))
		Ø3.4	0°: GH 0.5, 2.5, 4.5mm 15°: GH 0.5, 2.5mm 20°: GH 0.7mm
		Ø4.0	0°: GH 0.5, 2.5, 4.5mm 15°: GH 0.5, 2.5mm
		Ø5.0	0°: GH 2.5mm 15°: GH 0.5mm, 2.5mm
	Total Abutment Height [mm]	10.1 to 11.6	
	Design	Hexagonal connection / conical torx socket connection	
	Material	Titan Grade 5 (ISO 5832-3 / ASTM F136)	
	Surface	Anodized	

Esthetic Abutments			
	Packaging / Sterilization	Packed in an individual PE bag - Must be sterilized by the user.	
End User Modification		Wall thickness/diameter	No modifications allowed
		Post height	Shortening to a minimum Abutment Post Height of 5 mm allowed
		Angulation and divergence	No modifications allowed
		Gingival height	No modifications allowed
		Connection platform	No modifications allowed
		Method of modification	Hand Tools only

4.2.2. Wide Body Abutments

BoneTrust® Wide Body Abutments are premanufactured single-piece abutments constructed of titanium alloy per ISO 5832-3 and intended to be used for cemented single-tooth and bridge restorations as well as temporary single tooth restorations.

Wide Body Abutment and Wide Body Abutment cone+ feature bigger body diameter compared to the Esthetic Abutment / Esthetic Abutment cone+ which allows the option of switching to a wider prosthetic platform

The abutment might be shortened up to a minimum abutment post height of 5 mm. the abutments are not intended for angular correction, correction of diameter or taper

Wide Body Abutments			
	**Angulation (°)**	0	
	Available Sizes	Platform Diameter	Gingival Height (GH)
		3.4 mm / 4.0 mm	3.0 mm
		5.0 mm	3.0 mm
	Total Abutment Height [mm]	11.2 to 12.2	
	Design	Hexagonal connection / conical torx socket connection	
	Material	Titan Grade 5 (ISO 5832-3 / ASTM F136)	
	Surface	Anodized	
	Packaging / Sterilization	Packed in an individual PE bag - Must be sterilized by the user.	
	End User Modification	Wall thickness/diameter	No modifications allowed
		Post height	Shortening to a minimum Abutment Post Height of 5 mm allowed
		Angulation and divergence	No modifications allowed
		Gingival height	No modifications allowed
		Connection platform	No modifications allowed
		Method of modification	Hand Tools only

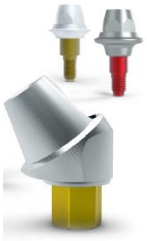
4.2.3. UCLA Abutments

BoneTrust® UCLA Abutments are intended to be used as a pattern for the creation of customized veneered crowns for cemented or screw retained single-tooth and bridge restorations. BoneTrust® UCLA Abutments are available in the following shapes:

UCLA Abutments		
	Angulation [°]	0
	Platform Diameter [mm]	3.4 / 4.0 / 5.0
	Body Diameter [mm]	2.8
	Cylinder Height [mm]	3.0
	Design	Hexagonal connection with / without rotation stop Conical torx socket connection with / without rotation stop
	Material for Precious Alloys	Heraplat Au 61%, Pt 23.8 %, Pd 15 %, Rh 0.2 %
	Material for Non Precious Alloys	PtIr20% (ISO 22674)
	Surface	Anodized
	Packaging / Sterilization	Packed in an individual PE bag - Must be sterilized by the user.
	End User Modification	No modification allowed to the abutment Burn-out plastic sleeve may be shortened down to a minimum height of 4 mm

4.2.4. Direct Abutment

BoneTrust® Direct Abutments are premanufactured multi-unit abutments constructed of titanium alloy per ISO 5832-3 and intended to be used for splinted and occlusally screwed prosthetics, such as bridges, hybrid prostheses and cast bars,. BoneTrust® Direct Abutments are two piece abutments intended for use in combination with Auro Base Direct Abutments. BoneTrust® Direct Abutments are available in the following shapes:

Direct Abutments			
	**Available Sizes**	**Angulation**	**Size (diameter in mm x Gingival Height in mm)**
		0°	**3.4/4.0 x GH 1.0** **3.4/4.0 x GH 3.0**
		20°	**3.4/4.0 x GH 2.0**
		30°	**3.4/4.0 x GH 2.0**
	Total Abutment Height [mm]	9.1 to 12.2	
	Design	Hexagonal connection / conical torx socket connection	
	Material	Titan Grade 5 (ISO 5832-3 / ASTM F136)	
	Surface	Anodized	
	Compatible Abutments	BonteTrust® Direct Healing Abutments BoneTrust® AuroBase Abutments	
	Packaging / Sterilization	packed in an individual PE bag - Must be sterilized by the user.	
	End User Modification	No modification allowed	

4.2.5. AuroBase Direct Abutments

BoneTrust® AuroBase Direct Abutments are premanufactured multi-unit abutments intended to be used as a pattern for the creation of customized veneered crowns for splinted and occlusally screwed prosthetics, such as bridges, hybrid prostheses and cast bars. BoneTrust® AuroBase Direct Abutments are two piece abutments intended for use in combination with Direct Abutments.

Auro Base Abutment		
	**Angulation (°)**	0
	Cylinder Height (mm)	3.2
	Platform diameter D (mm)	3.4 / 4.0
	Body diameter (mm)	3.15
	Design	Hexagonal connection / conical torx socket connection
	Material for Precious Alloys	Heraplat Au 61%, Pt 23.8 %, Pd 15 %, Rh 0.2 %
	Material for Non Precious Alloys	PtIr20% (ISO 22674)
	Surface	Anodized
	Compatible Abutments	BonteTrust® Direct Abutments
	Packaging / Sterilization	packed in an individual PE bag - Must be sterilized by the user.
	End User Modification	No modification allowed to the abutment Burn-out plastic sleeve may be shortened down to a minimum height of 4 mm

4.2.6. Telescopic Abutment

BoneTrust® Telescopic Abutments are constructed of titanium alloy per ISO 5832-3 and intended to be used for fixation of friction retained removable restorations and bridges. BoneTrust® telescopic Abutments are available with hexagon or conical torx connection with 3.4 / 4 mm Platform.

Telescopic Abutment			
	**Angulation (°)**	0	
	Platform diameter D (mm)	3.4 / 4	
	Body diameter (mm)	5	
	Total Abutment Height [mm]	8.0 to 10.8	
	Design	Hexagonal connection / conical torx socket connection	
	Material	Titan Grade 5 (ISO 5832-3 / ASTM F136)	
	Surface	Anodized	
	Packaging / Sterilization	packed in an individual PE bag - Must be sterilized by the user.	
	End User Modification	Wall thickness/diameter	No modifications allowed
		Post height	No modifications allowed
		Angulation and divergence	Maximum Taper of 5° to correct divergence between implants
		Gingival height	No modifications allowed
		Connection platform	No modifications allowed
		Method of modification	Hand Tools only

4.2.7. Healing Abutment

BoneTrust® Healing Abutments are premanufactured abutments constructed of titanium alloy per ISO 5832-3 and intended to be used temporarily during the healing period of the BoneTrust® implant to prepare gingival tissue for acceptance of the final abutment. BoneTrust® Healing Abutments are available in the following shapes:

Healing Abutment			
	**Angulation (°)**	0	
	Available Sizes	Platform Diameter	Gingival Height (GH)
		3.4 mm	1.5 mm, 3.0 mm, 5.0 mm, 7.0 mm
		4.0 mm	1.5 mm, 3.0 mm, 5.0 mm
		5.0 mm	1.5 mm, 3.0 mm, 5.0 mm
	Total Abutment Height [mm]	6.5 to 12.6	
	Design	Hexagonal connection / conical torx socket connection	
	Material	Titan Grade 5 (ISO 5832-3 / ASTM F136)	
	Surface	Anodized	
	Packaging / Sterilization	packed in an individual PE bag - Must be sterilized by the user.	
	Maximum intraoral Use	180 Days	
	Load	Non-occlusal load	

4.2.8. Direct Healing Abutment

BoneTrust® Direct Healing Abutments are premanufactured abutments designed to be mounted on BoneTrust® Direct Abutments. They are constructed of titanium alloy per ISO 5832-3 and indicated for use with the BoneTrust® Direct Abutments during the healing period of the BoneTrust® implant to prepare gingival tissue for acceptance of the final abutment. They are intended for use of up to 180 days during endosseous and gingival healing and are for non-occlusal loading of provisional restorations. BoneTrust® Direct Healing Abutments are available in the following shapes:

Direct Healing Abutment		
	Angulation [°]	0
	Diameter [mm]	4.9
	Length [mm]	4.75
	Material	Titan Grade 5 (ISO 5832-3 / ASTM F136)
	Surface	Anodized
	Packaging / Sterilization	Packed in an individual PE bag - Must be sterilized by the user.
	Maximum Intraoral Use	180 Days
	Load	Non-occlusal load

4.2.9. Healing Abutments Wide Body

BoneTrust® Wide Body Healing Abutments are premanufactured abutments constructed of titanium alloy per ISO 5832-3 and indicated for use with the BoneTrust® Implant System during the healing period of the BoneTrust® implant to prepare gingival tissue for acceptance of the final abutment. They are intended for use of up to 180 days during endosseous and gingival healing and are for non-occlusal loading of provisional restorations. BoneTrust® Healing Abutments Wide Body are available in the following shapes:

Healing Abutment - Wide Body			
	**Angulation (°)**	0	
	Available Sizes	Platform Diameter	Gingival Height (GH)
		3.4 mm / 4.0 mm	3.0 mm, 5.0 mm
		5.0 mm	3.0 mm, 5.0 mm
	Total Abutment Height [mm]	8.6 to 10.6	
	Design	Hexagonal connection / conical torx socket connection	
	Material	Titan Grade 5 (ISO 5832-3 / ASTM F136)	
	Surface	Anodized	
	Packaging / Sterilization	packed in an individual PE bag - Must be sterilized by the user.	
	Maximum intraoral Use	180 Days	
	Load	Non-occlusal load	

5. Indications for Use

BoneTrust® Dental Implants are medical devices intended to be surgically placed in the bone of the maxillary and/or mandibular arches to provide support for prosthetic restorations (crowns, bridges or overdenture) in edentulous or partially edentulous patients to restore a patients' chewing function.

Bone Trust® implants can also be used for immediate loading when sufficient primary stability is achieved and with appropriate occlusal loading.

BoneTrust® Short Dental Implants with length 6.5 mm are intended for delayed loading only

BoneTrust® Abutments and Prosthetic parts are intended for use with Bone Trust Dental Implants in the maxillary and/or mandibular arches to provide support for crowns, bridges or overdenture for edentulous or partially edentulous patients.

6. Technological Characteristics and Substantial Equivalence

6.1. Comparison of Indications for Use

The indications for use of the subject devices are compared to the primary predicate and reference devices in the following tables:

Company	Candidate: Medical Instinct Deutschland GmbH	Primary Predicate: Straumann AG	Discussion
Device Name	BoneTrust® Implant System	Dental Implant System – Roxolid® SLA Implants	--
510(K) number	--	K150938	--
Indications for Use	BoneTrust® Dental Implants are medical devices intended to be surgically placed in the bone of the maxillary and/or mandibular arches to provide support for prosthetic restorations (crowns, bridges or overdenture) in edentulous or partially edentulous patients to restore a patients' chewing function.	Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).	Both implant-systems are indicated for placement in the patient's jaw to provide support for prosthetic restorations in edentulous or partially edentulous patients The wording "maxillary and/or mandibular arches" has the same meaning as "upper and lower jaw." Further minor differences in language do not impact the safety and effectiveness of the subject device.
	Bone Trust® implants can also be used for immediate loading when sufficient primary stability is achieved and with appropriate occlusal loading.		Booth Implant Systems may be used for immediate loading when good primary stability is achieved. Minor differences in language do not impact the safety and effectiveness of the subject device.
	BoneTrust® Short Dental Implants with length 6.5 mm are intended for delayed loading only		The inclusion of 6.5mm length specific language does not impact the safety and effectiveness of the subject device.
	BoneTrust® Abutments and Prosthetic parts are intended for use with Bone Trust Dental Implants in the maxillary and/or mandibular arches to provide support for crowns, bridges or overdenture for edentulous or partially edentulous patients.		Similar to primary predicate Indications for Use The wording "maxillary and/or mandibular arches" has the same meaning as "upper and lower jaw." Further minor differences in language do not impact the safety and effectiveness of the subject device. Further reference devices used for technological comparisons of BoneTrust® Abutments do not include any component-specific language that would raise any concern related to the safety and effectiveness of the subject devices. Further minor differences in language do not impact the safety and effectiveness of the subject device

6.2. Comparison of Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the following tables:

6.2.1. BoneTrust® plus/cone+ implant

Company	**Candidate: Medical Instinct Deutschland GmbH**	**Primary Predicate: Straumann AG**	**Reference Device: SIC Invent AG**	**Discussion**
Device Name	BoneTrust plus/cone+ implant	Dental Implant System – Roxolid® SLA Implants	SIC Ace / Max Implants	--
510(K) number	--	K150938	K173207	--
Implant material	Titan Grade 4 ASTM F67	Titanium Grade 4	Titanium Grade 4	Identical
Implant Type	Screw-type	Screw-type	Screw-type	Identical
Design	Conical	Conical	Conical	Identical
Load	Delayed and Immediate	Delayed and Immediate	Delayed and Immediate	Identical
Unit restoration	Partial or total tooth loss	Partial or total tooth loss	Partial or total tooth loss	Identical
Single or two piece	Two pieces	Two pieces	Two pieces	Identical
Screw type	Self-threading	Self-threading	Self-threading	Identical
Distal end	With thread	With thread	With thread	Identical
Implant to abutment connection	Cylindrical Internal Hexagon or conical torx	Narrow Neck CrossFit® (NNC) Regular Neck (RN) Wide Neck (WN)	Hex 2.3 Morse Taper	Results of fatigue testing support that differences do not raise any concerns in regard to safety and effectiveness of the implant abutment interface.

Company	Candidate: Medical Instinct Deutschland GmbH	Primary Predicate: Straumann AG	Reference Device: SIC Invent AG	Discussion
Implant Dimen-sions (Diameter X Length)	Ø3.4 X 8 Ø3.4 X 10 Ø3.4 X 11,5 Ø3.4 X 13 Ø3.4 X14,5 Ø4 X 6.5 Ø4 X 8 Ø4 X 10 Ø4 X 11.5 Ø4 X 13 Ø4 X 14.5 Ø5 X 6.5 Ø5 X 8 Ø5 X 10 Ø5 X 11.5 Ø5 X 13	Ø3.3 X 8 Ø3.3 X 10 Ø3.3 X 12 Ø3.3 X 14 Ø4.1 X 6 Ø4.1 X 8 Ø4.1 X 10 Ø4.1 X 12 Ø4.1 X 14 Ø4.8 X 6 Ø4.8 X 8 Ø4.8 X 10 Ø4.8 X 12 Ø4.8 X 14	Ø3.4 / 3.7 X 7.5 Ø3.4 / 3.7 X 9.5 Ø3.4 / 3.7 X 11,5 Ø3.4 / 3.7 X 13 Ø3.4 / 3.7 X14,5 Ø4.0 / 4.2 X 6.0 Ø4.0 / 4.2 X 7.5 Ø4.0 / 4.2 X 9.5 Ø4.0 / 4.2 X 11.5 Ø4.0 / 4.2 X 13.0 Ø4.0 / 4.2 X 14.5 Ø4.5 / 4.7 X 6.0 Ø4.5 / 4.7 X 7.5 Ø4.5 / 4.7 X 9.5 Ø4.5 / 4.7 X 11.5 Ø4.5 / 4.7 X 13.0 Ø4.5 / 4.7 X 14.5 Ø5.0 / 5.2 / 4.7 X 6.0 Ø5.0 / 5.2 / 4.7 X 7.5 Ø5.0 / 5.2 / 4.7 X 9.5 Ø5.0 / 5.2 / 4.7 X 11.5 Ø5.0 / 5.2 / 4.7 X 13 Ø5.0 / 5.2 / 4.7 X 14.5	Reference device has been used to address any dimen-sions not cleared in the primary predi-cate submission.
Surface treatment	blasted-etched	SLA grit blast and acid etch surface	blasted-etched	Results of non-clinical testing sup-port that differences in surface character-istics do not raise any concerns in regard to safety and effectiveness of the proposed devices

6.2.2. Esthetic Abutments

Company	Candidate: Medical Instinct Deutschland GmbH	Reference Device: Altatech GmbH	Discussion
Device Name	BoneTrust® Esthetic Abutments	CAMLOG Abutments	--
510(K) number	--	K083496	--
Material	Titanium alloy TiAl4V	Titanium alloy TiAl4V	Identical
Surface	Anodized surface	Anodized surface	Identical
Size	Ø3.4: 0°: GH 0.5, 2.5, 4.5mm 15°: GH 0.5, 2.5mm 20°: GH 0.7mm Ø4.0: 0°: GH 0.5, 2.5, 4.5mm 15°: GH 0.5, 2.5mm Ø5.0: 0°: GH 2.5mm 15°: GH 0.5mm, 2.5mm Total Abutment height: 10.1 mm, 11.6 mm	Platform Diameter: ø 3.3 - 3.8 - 4.3 - 5.0 - 6.0 mm Body Diameter: 4.5 to 8.0 mm Gingival Height: 0.8 - 1.0 - 1.8 - 2.5 - 3.0 - 4.5 mm Total Abutment height: 8.7 mm - 11.7 mm	Substantially equivalent Sizes are within range of the Reference Device, except Gingival Height (GH) of 0.5 / 0.7mm. This difference does not raise any concerns in regard to safety and effectiveness of the proposed devices
Connection	Cylindrical external Hexagon or and conical torx	Conical fitting	Results of dynamic fatigue testing support that differences in inner geometry do not raise any concerns in regard to safety and effectiveness of the implant abutment interface.
Angulation	0° - 15° - 20°	0° - 15° - 20°	Identical

6.2.3. Wide Body Abutments

Company	Candidate: Medical Instinct Deutschland GmbH	Reference Device: Altatech GmbH	Discussion
Device Name	BoneTrust® Wide Body Abutments	CAMLOG Abutments	--
510(K) number	--	K083496	--
Material	Titanium alloy TiAl4V	Titanium alloy TiAl4V	Identical
Surface	Anodized surface	Anodized surface	Identical
Size	Platform Diameter: ø 3.4 - 4.0 - 5.0 mm Body Diameter: 7.4 / 7.6 mm Gingival Height: 3.0 mm Total Abutment height: 11.2 mm, 11.6 mm	Platform Diameter: ø 3.3 - 3.8 - 4.3 - 5.0 - 6.0 mm Body Diameter: 4.5 to 8.0 mm Gingival Height: 0.8 - 1.0 - 1.8 - 2.5 - 3.0 - 4.5 mm Total Abutment height: 8.7 mm - 11.7 mm	Sizes are within range of Reference Device,

Connection	Cylindrical external Hexagon or and conical torx	Conical fitting	Results of dynamic fatigue testing support that differences in inner geometry do not raise any concerns in regard to safety and effectiveness of the implant abutment interface
Angulation	0°	0° - 15° - 20°	within range of Reference device

6.2.4. UCLA Abutments

Company	**Candidate: Medical Instinct Deutschland GmbH**	**Reference Device: Institut Straumann AG**	**Reference Device Biomet 3i**	**Discussion**
Device Name	BoneTrust® Abutments	RN synOcta UCLA Gold Abutment	UCLA Gold / castable Abutment	--
510(K) number	--	K041295	K072642	--
Material	Heraplat Au 61%, Pt 23,8%, Pd, 15% Rh 0,2% / Platinum-Iridium-alloy (PtIr20%)	Ceramicor® Au 60%, Pd 20%, Pt 19%, Ir 1%	Machined Gold Alloy	Materials conform to ISO 22674 standard. Biocompatibility Assessment and testing support substantial equivalence to reference device
Material Burn out-sleeve	POM	POM	Plastic	Identical to K041295
Size	Diameter ø 3.4, 4.0, 5.0 mm Cylinder height: 3 mm	Diameter: 4.8, 6.5 Cylinder height: 1.8 – 3.35 mm	Diameter ø 3.4, 4.1, 5.0, 6.0 mm Cylinder height: 4 mm	Diameters are within the range of K072642, Cylinder Heights and total heights are similar to K041295
Surface	Anodized	Anodized	Anodized	Identical
Connection	Cylindrical external Hexagon or conical torx	SynOcta connection Cone -octagon	Hexed and non-hexed connection	Results of dynamic fatigue testing support that differences in inner geometry do not raise any concerns in regard to safety and effectiveness of the implant abutment interface

6.2.5. Direct Abutment

Company	**Candidate: Medical Instinct Deutschland GmbH**	**Reference Device: Nobel Biocare AB**	**Discussion**
Device Name	BoneTrust® Abutments	NobelActive Multi Unit Abutment – Gold Coping Multi-Unit Abutment	--
510(K) number	--	K072570	--
Material	Titanium alloy TiAl4V	CP titanium (Grade 4) Titanium alloy TiAl4V	Identical

Surface	Anodized surface	machined	Results of biocompatibility assessment and testing support that differences in surface treatment do not raise any concerns in regard to safety and effectiveness of the proposed device
Size	Diameter ø 3.4, 4.0, 5.0 mm Gingival Height: 1, 2, 3 mm Total height: 9.1, 9.4 mm	Diameter ø 3.5, 4.3, 5.0 mm Gingival Height: 1, 2, 3, 4, 5 mm Total height: not known	Platform Sizes are adapted to platform diameter of the implant system. Minor differences do not raise any concerns in regard to safety and effectiveness of the proposed device
Connection	Cylindrical external Hexagon or and conical torx	External Hex, Conical	Results of dynamic fatigue testing support that differences in inner geometry do not raise any concerns in regard to safety and effectiveness of the implant abutment interface
Angulation	0°, 20°, 30°	0°, 17°, 30°	Within range of Reference Device

6.2.6. Auro Base Abutment

Company	**Candidate:** **Medical Instinct Deutschland GmbH**	**Reference Device:** **Nobel Biocare AB**	**Discussion**
Device Name	BoneTrust® Abutments	NobelActive Multi Unit Abutment – Gold Coping Multi-Unit Abutment	--
510(K) number	--	K072570	--
Material	Heraplat Au 61%, Pt 23,8%, Pd, 15% Rh 0,2% / Platinum-Iridium-alloy (PtIr20%)	Au 60%, Pd 20%, Pt 19%, Ir 1%	Materials conform to ISO 22674 standard. Biocompatibility Assessment and testing support substantial equivalence to reference device
Material Burn out sleeve	POM	Burn out plastic	Substantially equivalent
Surface	Machined	machined	Identical
Size	Cylinder Height [mm]: 3.2 Platform Diameter [mm]: 3.4 / 4.0 Body Diameter [mm]: 3.1	Cylinder Height [mm]: 3.0 Platform Diameter [mm]: ø 3.5, 4.3, 5.0 mm Body Diameter [mm]: not known	Results of dynamic fatigue testing support that differences in Abutment size do not raise any concerns in regard to safety and effectiveness of the proposed device

Connection	Cylindrical external Hexagon or and conical torx	External Hex, Conical	Results of dynamic fatigue testing support that differences in inner geometry do not raise any concerns in regard to safety and effectiveness of the implant abutment interface
Angulation	0°	0°	Identical

6.2.7. Telescopic Abutment

Company	**Candidate: Medical Instinct Deutschland GmbH**	**Reference Device: Altatech GmbH**	**Reference Device Dentsply Implants GmbH**	**Discussion**
Device Name	BoneTrust® Telescopic Abutments	CONELOG Telescopic Abutments	Friadent Telescopic Abutment	--
510(K) number	---	K113779	K021318	--
Material	Titanium alloy TiAl4V	Titanium alloy TiAl4V	Titanium alloy TiAl4V	Identical
Surface	Machined surface	Machined surface	Machined surface	Identical
Connection	Cylindrical external Hexagon or conical torx	Conical fitting	Hexagon connection	Results of dynamic fatigue testing support that differences in inner geometry do not raise any concerns in regard to safety and effectiveness of the implant abutment interface
Size	Diameter: 3,4 / 4 mm	Diameters: 3.8, 4.3, 5.0, and 6.0 mm	Diameters: 3.4, 3.8, 4.5, 5.5 mm	Within range of K021318
Maximum Taper	5°	5°	Not known	identical to K113779

6.2.8. Healing Abutment

Company	**Candidate: Medical Instinct Deutschland GmbH**	**Reference Device: SIC Invent AG**	**Discussion**
Device Name	BoneTrust® Healing Abutments	SIC Gingiva Shaper	--
510(K) number	--	K173207	--
Maximum intraoral use	180 Days	180 Days	Identical
Load	Non-occlusal loading	Non-occlusal loading	Identical
Material	Titanium alloy TiAl4V	Titanium alloy TiAl4V	Identical
Surface	anodized surface	anodized surface	Identical
Connection	Cylindrical external Hexagon or conical torx	Conical or cylindrical fitting	Results of dynamic fatigue testing support that differences in inner geometry do not raise any concerns in regard to safety and effectiveness of the implant – abutment interface

Size	Platform Diameter	Gingival Height (GH)	Platform Diameter	Gingival Height (GH)	Reference device does not include a device with platform diameter equal to or smaller than 3.4 mm with a gingival height of 7.0 mm. The inclusion of a Ø3.4x7.0 mm Healing Abutment does not impact safety and effectiveness as healing abutments are placed out of occlusion. The gingival height is only to shape the gingi-va, not withstand load
	3.4 mm	1.5 mm, 3.0 mm, 5.0 mm, 7.0 mm	3.0 mm	1.0 mm, 2.0 mm, 3.0 mm, 4.0 mm, 5.0 mm,	
	4.0 mm	1.5 mm, 3.0 mm, 5.0 mm	3.7 mm	1.0 mm, 1.5 mm, 2.0 mm, 3.0 mm, 4.0 mm, 5.0 mm, 7.0 mm	
	5.0 mm	1.5 mm, 3.0 mm, 5.0 mm	4.2 / 4.7 / 5.2 mm	1.0 mm, 1.5 mm, 2.0 mm, 3.0 mm, 4.0 mm, 5.0 mm, 7.0 mm	

6.2.9. Direct Healing Abutment

Company	**Candidate:** **Medical Instinct Deutschland GmbH**	**Reference Device:** **Nobel Biocare USA LLC**	**Discussion**
Device Name	BoneTrust® Direct Healing Abutments	Healing Cap Multi-Unit Titanium	--
510(K) number	--	K171142	--
Maximum intraoral use	180 Days	180 Days	Identical
Load	Non-occlusal loading	Non-occlusal loading	Identical
Material	Titanium alloy TiAl4V	Titanium alloy Ti6Al4V ELI (ASTM F136)	Identical
Surface	anodized surface	anodized surface	Identical
Connection	Cylindrical external Hexagon or and conical torx	Conical fitting	Results of dynamic fatigue testing support that differences in inner geometry do not raise any concerns in regard to safety and effectiveness of the implant – abutment interface
Size	Healing Cap Height: 4.75 mm Healing Cap Diameter 4.9 mm	Healing Cap Height: 4.1 and 5.5 mm Healing Cap Diameter 5.0, 6.0, 6.9 mm	Sizes are within range of K171142, except Healing Cap Diameter is 0.1 mm smaller. This difference is due to the specific fitting to the abutment and does not raise any concerns in regard to safety and effective-ness of the proposed devices
Compatible Abutments	Bone Trust® Direct Abutments	Nobel Biocare Multi Unit Abutments	Adapted to fit manu-facturer's abutment system

6.2.10. Healing Abutment Wide Body

Company	Candidate: Medical Instinct Deutschland GmbH		Reference Device: Straumann USA	Discussion
Device Name	BoneTrust® Healing Abutments Wide Body		Healing Abutment	--
510(K) number	--		K130808	--
Maximum intraoral use	180 Days		180 Days	Identical
Load	Non-occlusal loading		Non-occlusal loading	Identical
Material	Titanium alloy TiAl4V		Titanium alloy Ti6Al4V ELI (ASTM F136)	Identical
Surface	anodized surface		anodized surface	Identical
Connection	Cylindrical external Hexagon or and conical torx		Conical fitting	Results of dynamic fatigue testing support that differences in inner geometry do not raise any concerns in regard to safety and effectiveness of the implant – abutment interface
Size	Platform Diameter	Gingival Height (GH)	Plattform Diameters: 3.3mm, 3.5mm, 4.1mm, 4.8mm, 6.5mm Gingival Heights: 2.0mm, 3.5mm, 4.0mm, 5.0mm, 6.0 mm	Within range of reference device
	3.4 mm / 4.0 mm	3.0 mm, 5.0 mm		
	5.0 mm	3.0 mm, 5.0 mm		

7. Performance testing

7.1. Summary of Clinical Testing

No clinical studies were performed for the BoneTrust® Implant System

7.2. Summary of non-Clinical Testing

The following nonclinical testing data were provided or relied upon in support of the substantial equivalence determination.

7.2.1. Biocompatibility

Biocompatibility assessment has been performed according to ISO 10993 series and included testing for cytotoxicity according to ISO 10993-5.

Results support substantial equivalence of the BoneTrust® implants to legally marketed predicate devices.

7.2.2. Fatigue testing

Fatigue testing of the implant-abutment interface has been tested for representative samples in accordance with ISO 14801.

Results support substantial equivalence of the BoneTrust® implants to legally marketed predicate devices.

7.2.3. Sterilization

Validation of sterilization instructions for non-sterile devices have been conducted according to ISO 17665-1 and ISO 17665-2 for pre-vacuum steam sterilization (wrapped cycle) demonstrating a sterility assurance level (SAL) of 10^{-6}.

Sterilization validation for device delivered sterile has been conducted according to ISO 11137-1 and 11137-2 for Beta-radiation sterilization. Shelf life testing has been conducted according to ISO 11607-1 and ASTM F1980 under consideration of accelerated and real-time ageing conditions. LAL testing was conducted according to USP 85 and the FDA Guidance “Submission and Review of Sterility information in Premarket Notification 510k Submissions for Devices Labeled as Sterile."

7.2.4. Implant Surface Analysis

Investigation of the implant surface included Energy Dispersive X-ray Spectroscopy (EDX), SEM (Scanning Electron Microscopy) and BSE (Back-Scattered-Electrons / secondary electrons analysis. Results support substantial equivalence of the BoneTrust® implants to legally marketed predicate devices.

7.2.5. Non-clinical Performance Data BoneTrust® Short Implants

In order to verify substantial equivalence to already marketed devices, BoneTrust® short implants were subjected to the following non-clinical performance studies:

- Comparative Surface area analysis
- Comparative Bone-to-implant contact study using animal histology
- Comparative pull-out strength test

Results support substantial equivalence of the BoneTrust® short implants to legally marketed predicate devices.

8. Conclusion as to Substantial Equivalence

Based on the comparison of the indications for use, the technological characteristics and the nonclinical testing it can be concluded that the BoneTrust® Implant System is substantially equivalent to the predicate devices.