May 14, 2021

Medical Instinct Deutschland GmbH
℅ André Weingerl
RA Consultant
WRC Consulting
Am Hohstetter 1a
Steißlingen, Baden Württemberg 78256
GERMANY

Re: K200573
Trade/Device Name: BoneTrust® Mini Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 8, 2021
Received: April 12, 2021

Dear André 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200573

Device Name
BoneTrust® Mini Implant System

Indications for Use *(Describe)*
The BoneTrust® Mini and Mini+ Implants are intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implant(s). Use of BoneTrust® Mini and Mini+ Implants is not to exceed one hundred and eighty (180) days.

BoneTrust® Mini Esthetic abutments and BoneTrust® Mini Crown Base Abutments are intended for use with BoneTrust® Mini / Mini+ Dental Implants to provide support for provisional prosthetic reconstructions during the healing phase of permanent endosseous dental implants. Use of BoneTrust® Mini Esthetic abutments and BoneTrust® Mini Crown Base Abutments is not to exceed one hundred and eighty (180) days.

BoneTrust® Mini Ball Attachments are intended to be used with BoneTrust® Mini / Mini+ Dental Implants to support and/or retain provisional removable dental prostheses during the healing phase of permanent endosseous dental implants. Use of BoneTrust® Ball Attachments is not to exceed one hundred and eighty (180) days.

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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K200573

VOLUME 006

510(k) Summary

Date of Submission 2021-14-05

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1. Device Name

Trade Name:	BoneTrust® Mini Implant System
Classification Name:	Endosseous dental implant - Endosseous dental implant abutment

2. Classification Product Code / Subsequent Code

BoneTrust® Mini 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(s)

- **Primary Predicate Device**

EM Provisional; Hiossen, Inc.	#K191751

- **Reference Devices**

Sterngold 2.2mm Angled Micro ERA Dental Implant System, Sterngold	#K092434
BoneTrust® Implant Systems, Medical Instinct Deutschland GmbH	#K182313
MIS LOCKiT Abutments System, OT-Equators and Ball Attachments, MIS Implants Technologies Ltd.	#K182228
Temporary Snap Abutment, Nobel Biocare AB	#K161435
MS SA Implant System, OSSTEM Implant Co. Ltd.	#K122171

4. Device Description

The BoneTrust® Mini Implant System is a two-piece dental implant system including various sizes of threaded root-form dental implants and abutments to provide temporary support of prosthetic restorations in edentulous or partially edentulous patients during the healing phase of permanent endosseous dental implant(s). The maximum duration of intraoral use of all members of the BoneTrust® Mini Implant System is 180 days

4.1. Implants Description

The BoneTrust® Mini Implants are root form implants manufactured from commercially pure titanium (Grade 4) per ISO 5832-2 and are supplied either with a machined surface or a sand-blasted, acid-etched surface treatment. All BoneTrust® Mini Implant types feature an external torx connection for fitment of BoneTrust® Mini cement-type abutments or ball type attachments

The following types of BoneTrust® Mini Implants are available:

BoneTrust® Mini implant

The BoneTrust® Mini Implant is a self-tapping straight body implant manufactured from commercially pure titanium with a machined surface. The implant features an external torx Implant-abutment connection.

BoneTrust® Mini+ Implant

The BoneTrust® Mini+ Implant is a self-tapping tapered body implant manufactured from commercially pure titanium with a microstructured surface by means of sandblasting / acid-etching surface-treatment followed by passivation. The implant features an external torx Implant-abutment connection.

Description	BoneTrust® Mini implant	BoneTrust® Mini+ Implant
Design / Shape	Screw type implant, straight Body, self-tapping	Screw type implant, tapered Body, self-tapping
Sizes - Diameter x length (mm)	2.3 x 11.5 2.3 x 13.0	2.5 x 10.0 2.5 x 13.0
Cuff height (mm)	2.25	3.50
Material	Unalloyed titanium grade 4 (ISO 5832-2:1999 / ASTM F67-06:2006)	Unalloyed titanium grade 4 (ISO 5832-2:1999 / ASTM F67-06:2006)
Surface	Machined surface	Microstructured blasted etched surface passivated
Prosthetic Platform	Ball Attachment (Denture O-Ball), Abutments for temporary cement-type restorations	Ball Attachment (Denture O-Ball), Abutments for temporary cemented restorations
Abutment Connection	External Torx Connection	External Torx Connection
Packaging / Sterilization	Sterile packed in blister; Sterilized by irradiation	Sterile packed in blister; Sterilized by irradiation
Duration of use	Max 180 days	Max 180 days

4.2. Abutments

BoneTrust® Mini Abutments are pre-manufactured single-piece Abutments directly connected to the BoneTrust® Mini Dental Implants and intended for use as an aid in the temporary prosthetic rehabilitation during the healing phase of permanent dental implants. BoneTrust® mini Abutments include Ball-type connections intended for support of removable overdentures and bridges as well as Cement-type connections for fixed temporary prosthetic restorations.

4.2.1. BoneTrust® Mini Esthetic Abutment

The BoneTrust® Mini Esthetic Abutments are pre-manufactured Abutments manufactured from Ti-6Al-4V Alloy as per ISO 5832-3 / ASTM F136 standard. The Abutments are available in straight shape. They are characterized by an anatomical garland-shaped course which replaces the need for customization to a greatest possible extent. They are intended for single tooth restoration as well as bridge restorations. The abutment might be shortened up to a minimum abutment post height of 4 mm. The abutments are not intended for angular correction, correction of diameter or taper.

Description	**Mini Esthetic Abutment**	
Angulation (°)	0	
Available Sizes	Platform Diameter	Gingival Height (GH)
	2.7 mm	1.0 mm
Total Abutment Height [mm]	5.5	
Design	External torx connection	
Material	Titanium alloy Ti-6Al-4V (ISO 5832-3 / ASTM F136)	
Surface	Machined	
Packaging / Sterilization	packed in an individual PE bag - Must be sterilized by the user.	
Duration of use	Max 180 days	
End User Modification	Wall thickness/diameter	No modifications allowed
	Post height	Shortening to a minimum Abutment Post Height of 4 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. BoneTrust® Mini Crown Base Abutment

BoneTrust® Mini Crown Base Abutments are premanufactured Abutments manufactured from Ti-6Al-4V Alloy as per ISO 5832-3 / ASTM F136 standard. The Abutments are available in straight shape and intended to be used for dentures and screw retained bridge constructions. The abutment might be shortened up to a minimum abutment post height of 4 mm. The abutments are not intended for angular correction, correction of diameter or taper.

Description	**Mini Crown Base Abutment**	
Angulation (°)	0	
Available Sizes	Platform Diameter	Gingival Height (GH)
	2.7 mm	1.0 mm
Total Abutment Height [mm]	7.5	
Connection Type	External torx connection	
Material	Titanium alloy Ti-6Al-4V (ISO 5832-3 / ASTM F136)	
Surface	machined	
Packaging / Sterilization	packed in an individual PE bag - Must be sterilized by the user.	
Duration of use	Max 180 days	
End User Modification	Wall thickness/diameter	No modifications allowed
	Post height	Shortening to a minimum Abutment Post Height of 4 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. BoneTrust® Mini Ball-Attachments

BoneTrust® Mini Ball-Attachments are indicated for the use of temporary non-splinted, removable dentures in the treatment of partially or totally edentulous patients to restore chewing function. They consist of the Ball type Attachment and the O-Ring matrix. The Ball type Attachment is manufactured from Ti-6Al-4V Alloy as per ISO 5832-3 / ASTM F136 standard with a machined surface. This attachment is mounted on the implant by a screw-locking mechanism and serves as the male part of the removable BoneTrust® Mini Ball-Attachment system. The retaining female counterpart, the O-ring matrix is manufactured from Ti-6Al-4V Alloy as per ISO 5832-3 / ASTM F136 with a machined surface. The O-Ring matrix is incorporated into an existing prosthesis via polymerization, engages the outside of the ball shape and allows retention of the prosthesis to the denture.

All components of the BoneTrust® Mini Ball-Attachment Abutments are not intended for any kind of modification by the user.

Description	**Mini Ball-Attachments**
Angulation (°)	0
Platform diameter (mm)	2.7
Body diameter (mm)	2.3
Connection Type	Internal locking screw fixation
Material	Titan Grade 5 (ISO 5832-3 / ASTM F136)
Surface	machined
Packaging / Sterilization	packed in an individual PE bag - Must be sterilized by the user.
Duration of use	Max 180 days

4.3. BoneTrust® Mini Retaining Screw

The BoneTrust® Mini Retaining Screw is manufactured from Ti-6Al-4V Alloy as per ISO 5832-3 / ASTM F136 standard with a machined surface. It is used to firmly connect BoneTrust® Mini Abutments with BoneTrust® Mini Implants via the implant's and abutment's torx-connection.

The BoneTrust® Mini Retaining Screw is delivered sterile and supplied with each BoneTrust® Mini Implant.

The BoneTrust® Mini Retaining Screw is not intended for any kind of modification by the user.

Description	**Mini Retaining Screw**
Angulation (°)	**0**
Total Length (mm)	4.4
Diameter (mm)	1.8
Connection Type	M1,4x0,25
Material	Titanium alloy Ti-6Al-4V (ISO 5832-3 / ASTM F136)
Surface	machined
Packaging / Sterilization	Sterile packed in blister; Sterilized by irradiation
Duration of use	Max 180 days

5. Indications for Use

The BoneTrust® Mini and Mini+ Implants are intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implant(s). Use of BoneTrust® Mini and Mini+ Implants is not to exceed one hundred and eighty (180) days.

BoneTrust® Mini Esthetic abutments and BoneTrust® Mini Crown Base Abutments are intended for use with BoneTrust® Mini / Mini+ Dental Implants to provide support for provisional prosthetic reconstructions during the healing phase of permanent endosseous dental implants. Use of BoneTrust® Mini Esthetic abutments and BoneTrust® Mini Crown Base Abutments is not to exceed one hundred and eighty (180) days.

BoneTrust® Mini Ball Attachments are intended to be used with BoneTrust® Mini / Mini+ Dental Implants to support and/or retain provisional removable dental prostheses during the healing phase of permanent endosseous dental implants. Use of BoneTrust® Ball Attachments is not to exceed one hundred and eighty (180) days.

6. Technological Characteristics and Substantial Equivalence

6.1. Comparison of indications for use and Technological Characteristics

The indications for use as well as technological characteristics of the proposed devices are compared to the primary predicate and reference devices in the following tables:

6.1.1. BoneTrust® Mini / Mini+ Implants

Company	**Proposed Device: Medical Instinct Deutschland GmbH**	**Primary Predicate Device: Hiossen Inc.**	**Reference Device: Sterngold**	**Reference Device: Medical Instinct Deutschland GmbH**	**Reference Device: OSSTEM Implant Co. Ltd.**	**Result**
Device Name	BoneTrust® Mini / Mini+ Implant System	**EM Provisional**	**Sterngold 2.2mm Angled Micro ERA Dental Implant System**	BoneTrust® Implant Systems	MS SA Implant System, Type: Narrow ridge	--
510(K) number	--	K191751	K092434	K182313	K122171	--
Intended use	The BoneTrust® Mini and Mini+ Implants are intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implant(s). Use of BoneTrust® Mini and Mini+ Implants is not to exceed one hundred and eighty (180) days.	The EM Provisional is intended to be loaded immediately in partially or fully edentulous mandibles and maxilla to serve as temporary support for provisional prosthetic device during the healing phase of permanent endosseous dental implant(s).	The Sternqold 2.2mm Angled ERA dental implants are intended for long term as well as temporary surgical implantation in the bone of the patient's upper or lower arch to provide immediate load or delayed load of prosthetic systems, such as artificial teeth, in order to restore the patient's chewing function. Immediate loading of the ERA Implant should only occur when the position of the implants provides adequate bone quantity and quality to allow proper immediate mechanical stabilization of the self-tapping screw into the bone and where occlusal and lateral forces can be limited with appropriate occlusal design and a soft diet.	Bone Trust® 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® Dental Implants are in-tended for immediate or delayed loading after 12 weeks.	The MIS SA Implant (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device; such as artificial teeth, in order to restore chewing function in partially edentulous patients. The MIS SA Implant (Narrow Ridge) is intended for single use only. It is intended for delayed loading	Similar to primary predicate device. The primary predicate device contains limitations of implant duration in the labeling. The additional limitation of implant duration is similar to reference devices and does not change the intended use of the device

Company	Proposed Device: Medical Instinct Deutschland GmbH	Primary Predicate Device: Hiossen Inc.	Reference Device: Sterngold	Reference Device: Medical Instinct Deutschland GmbH	Reference Device: OSSTEM Implant Co. Ltd.	Result
Implant material	Titanium Grade 4 ASTM F67	Titanium Grade 4 ASTM F67	Commercially pure Titanium	Titanium Grade 4 ASTM F67	Titanium Alloy Ti-6Al-4V (ASTM F 136)	Identical to reference device K182313
Implant Type	Screw-type	Screw-type	Screw-type	Screw-type	Screw-type	Identical
Design	straight body / tapered Body	straight body	straight body	straight body / tapered body	straight body	Identical to reference device K182313
Screw type	Self-tapping	Self-tapping	Self-tapping	Self-tapping	Self-tapping	Identical
Distal End	With thread	With thread	With thread	With thread	With thread	Identical
Single or two piece	Two piece design	One piece design	Two piece design	Two piece design	One piece design	Identical to reference devices K092434 and K182313
Implant to abutment connection	Eternal Torx Implant / Abutment fixture	Not applicable (One piece design)	External hex Implant / Abutment fixture	Cylindrical Internal Hexagon or and conical torx	Not applicable (One piece design)	The implant-Abutment connection geometry does not raise any concerns in regard to safety and effectiveness of the implant abutment interface

Company	Proposed Device: Medical Instinct Deutschland GmbH	Primary Predicate Device: Hiossen Inc.	Reference Device: Sterngold	Reference Device: Medical Instinct Deutschland GmbH	Reference Device: OSSTEM Implant Co. Ltd.	Result
Implant Dimensions (Diameter X Length)	Ø2.3 X 11.5 Ø2.3 X 13.0 Ø2.5 X 10.0 Ø2.5 X 13.0	Ø1.8 mm X 10.0 mm Ø1.8 mm X 13.0 mm Ø1.8 mm X 15.0 mm Ø2.5 mm X 10.0 mm Ø2.5 mm X 13.0 mm Ø2.5 mm X 15.0 mm	Ø2.2 mm X 10.0 mm Ø2.2 mm X 13.0 mm Ø2.2 mm X 15.0 mm	Ø3.4 X 8 Ø3.4 X 10 Ø3.4 X 11,5 Ø3.4 X 13 Ø3.4 X14,5 Ø 4 X 6.5 Ø4 X 8 Ø4 X 10 Ø4 X 11.5 Ø4 X 13 Ø4 X 14.5 Ø 5 X 6.5 Ø5 X 8 Ø5 X 10 Ø5 X 11.5 Ø5 X 13	Ø2.5 mm X 8.5 mm Ø2.5 mm X 10.0 mm Ø2.5 mm X 11.5 mm Ø2.5 mm X 13.0 mm Ø2.9 mm X 8.5 mm Ø2.9 mm X 10.0 mm Ø2.9 mm X 11.5 mm Ø2.9 mm X 13.0 mm	Sizes are within range of primary predicate device
Surface treatment	Machined / Microstructured blasted etched surface passivated	Machined	Microstrucured, acid-etched Surface	Microstructured blasted etched surface, passivated	Sand blasting and acid etching	Identical to K191751 and K182313
Sterilization	Beta Radiation	Gamma Radiation	Gamma Radiation	Beta Radiation	Radiation sterile	Identical to K182313

6.1.2. BoneTrust® Mini Esthetic Abutments / Mini Crown base Abutments

Company	Candidate: Medical Instinct Deutschland GmbH	Reference Device: Nobel Biocare AB	Reference Device: Sterngold	Reference Device: Medical Instinct Deutschland GmbH	Result
Device Name	BoneTrust® Mini Esthetic Abutments, Crown Base Abutments	Temporary Snap Abutment	**Sterngold 2.2mm Angled Micro ERA Dental Implant System**	BoneTrust® Esthetic Abutments	--
Code	NHA	NHA	DZE	NHA	--
510(K) number	--	K161435	K092434	K182313	--
Indications	BoneTrust® Mini Esthetic abutments and BoneTrust® Mini Crown Base Abutments are intended for use with BoneTrust® Mini / Mini+ Dental Implants to provide support for provisional prosthetic reconstructions during the healing phase of permanent endosseous dental implants. Use of BoneTrust® Mini Esthetic abutments and BoneTrust® Mini Crown Base Abutments is not to exceed one hundred and eighty (180) days.	The Temporary Snap Abutment is intended to be used to fabricate and support provisional restorations that aid in creating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Temporary Snap Abutment can be used for cement retained or screw-retained provisional restorations. The abutments can be used for single-unit and multi-unit restorations. Use of the temporary Snap Abutment is not to exceed one hundred and eighty (180) days.	The Sternqold 2.2mm Angled ERA dental implants are intended for long term as well as temporary surgical implantation in the bone of the patient's upper or lower arch to provide immediate load or delayed load of prosthetic systems, such as artificial teeth, in order to restore the patient's chewing function. Immediate loading of the ERA Implant should only occur when the position of the implants provides adequate bone quantity and quality to allow proper immediate mechanical stabilization of the self-tapping screw into the bone and where occlusal and lateral forces can be limited with appropriate occlusal design and a soft diet.	Bone Trust® 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.	Substantially Equivalent to K161435. Indications of K092434 include temporary and permanent use and thus cover all indications claimed for the proposed device. The more restrictive indications of the proposed device do not raise any concerns in regard to safety and effectiveness Minor differences in language do not impact the safety and effectiveness of the subject device

Company	Candidate: Medical Instinct Deutschland GmbH	Reference Device: Nobel Biocare AB	Reference Device: Sterngold	Reference Device: Medical Instinct Deutschland GmbH	Result
Duration of use	Temporary use	Temporary use	Temporary use / Permanent use	Permanent use	Identical to K161435 Indications of K092434 include temporary and permanent use and thus cover all indications claimed for the proposed device. The more restrictive indications of the proposed device do not raise any concerns in regard to safety and effectiveness
Material	Titanium alloy Ti6Al4V (ASTM F136)	Abutments and screws – Titanium vanadium alloy (ASTM F1472, ASTM F136)	Wrought Titanium 6AL-4V ELI	Titanium alloy Ti6Al4V (ASTM F136)	Identical
Surface	Machined	Machined	Machined	Machined	Identical
Size	Platform Diameter: 2.7mm Body Diameter: 3.9mm, 4.2mm Gingival Height: 1.0mm	Platform Diameter: Narrow Platform (NP), Regular Platform (RP), Wide Platform (WP) Body Diameter: 4.0, 4.5, 6.0mm Collar height: 1.5mm, 3mm	Platform Diameter: 2.2mm (Implant thread major diameter) Cuff Height: 0,76 – 4mm	Platform Diameter: ø 3.4 - 4.0 - 5.0mm Body Diameter: 4.5mm Gingival Height: 0.5 - 0.7 - 2.5 - 4.5mm	Reference device K092434 has been used to address any dimensions not cleared in the reference Device K161435 submission.

Company	Candidate: Medical Instinct Deutschland GmbH	Reference Device: Nobel Biocare AB	Reference Device: Sterngold	Reference Device: Medical Instinct Deutschland GmbH	Result
Connection	Eternal Torx Implant / Abutment fixture	Internal conical connection	Internal Connection	Cylindrical external Hexagon or conical torx	The implant-Abutment connection geometry does not raise any concerns in regard to safety and effectiveness of the implant abutment interface
Angulation	0°	0°	0°, 5°, 11°, 17°	0° - 15° - 20°	Identical to K161435
sterility	Unsterile	Unsterile	Unsterile	Unsterile	Identical

6.1.3. BoneTrust® Mini Ball Attachment

Company	Candidate: Medical Instinct Deutschland GmbH	Reference Device: MIS Implants Technologies Ltd.	Result
Device Name	BoneTrust® Ball Attachments	MIS LOCKiT Abutments System, OT-Equators and Ball Attachments	--
Code	NHA	NHA	--
510(K) number	--	K182228	--
Indications	BoneTrust® Mini Ball Attachments are intended to be used with BoneTrust® Mini / Mini+ Dental Implants to support and/or retain provisional removable dental prostheses during the healing phase of permanent endosseous dental implants. Use of BoneTrust® Ball Attachments is not to exceed one hundred and eighty (180) days.	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. For fully edentulous jaw retaining a tissue-supported overdenture.	Both devices are intended for the support of removable dental prostheses. Reference Device is indicated for long-term intraoral use, whereas the proposed device is indicated for provisional use. These differences do not impact the safety and effectiveness of the proposed device
Material	Titanium alloy Ti6Al4V (ASTM F136)	Ti 6Al 4V ELI per ASTM F136	Identical
Surface	machined	TiN coating after 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	Platform Diameter: 2.7mm Body Diameter: 4.5mm Gingival Height: 1.0mm	Platform Diameter: 3.3mm, 3.75mm, 4.2mm, 5.0mm, 6.0mm Body Diameter: 4.0mm, 4.1mm, 5.0mm Gingival Height: 1.0mm, 2.0mm, 3.0mm, 4.0mm, 5.0mm	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	Internal locking screw fixation	Internal hexagon	The implant-Abutment connection geometry does not raise any concerns in regard to safety and effectiveness of the implant abutment interface.
Angulation	0°	0°	Identical
sterility	Non Sterile	Non Sterile	Identical

7. Performance testing

7.1. Summary of Clinical Testing

No clinical studies were performed for the BoneTrust® Mini 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

BoneTrust® Mini Implants and prosthetic components are manufactured using the same manufacturing process and same well established materials as Implants and prosthetic components of the BoneTrust® Implant System previously cleared under #K182313. Therefore it is believed that additional biocompatibility testing in order to support the biological safety of the BoneTrust® Mini Implant System is not necessary.

7.2.1.1. Testing for Bacterial endotoxins

Periodic testing for bacterial endotoxins on BoneTrust® Mini Implants and prosthetic components is performed in accordance with USP <85> (limits 2.15 EU / sample). Historical test data has shown that BoneTrust® Mini implants continuously maintain acceptable levels of bacterial endotoxins. Therefore, a sampling plan including quarterly testing for endotoxins has been considered appropriate based on established process-consistency.

7.2.2. Fatigue testing.

The BoneTrust® Mini Implant system does not contain angulated abutments. As per FDA Guidance Document: Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments fatigue testing has not been deemed necessary to support substantial equivalence

7.2.3. Sterilization

The BoneTrust® Mini and Mini+ implants are Beta-radiation sterilized for a SAL (Sterility Assurance Level) of 10^{-6} with a validated sterilization procedure according to ISO 11137-1:2006 (Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices) and 11137-2:2013 (Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose).

The manufacturing, packaging final cleaning and sterilization process applied to the BoneTrust® Mini Implants is identical to the sterilization process for BoneTrust® Implants previously cleared under #K182313. Therefore it is believed that no additional validation studies are necessary to support sterilization efficacy of the BoneTrust® Mini Implants.

BoneTrust® Mini prosthetic components are delivered unsterile and intended to be sterilized by the end-user prior to their clinical use. Device design as well as indicated methods and process-parameters for end-user sterilization are identical to BoneTrust® prosthetic components previously cleared under #K182313. Therefore it is believed that no additional validation studies are necessary to support end-user sterilization efficacy of the BoneTrust® Mini prosthetic components.

7.2.4. Shelf life

BoneTrust® Mini and Mini+ Implants are delivered sterile with a shelf life of 5 years. The packaging system used for the BoneTrust® Mini Implants is identical to the packaging system used for the BoneTrust® implants previously cleared under #K182313. Therefore it is believed that no additional validation studies are necessary to support Shelf-Life of the BoneTrust® mini Implant packaging system. Instead, validation activities performed on the BoneTrust® Implants cleared under #K182313 apply to the BoneTrust® Mini Implants.

7.2.5. Implant Surface Analysis

BoneTrust® Mini and Mini+ Implants feature the same surface modification as BoneTrust® Implants, previously cleared under #K182313. Investigation of the implant surface included Energy Dispersive X-ray Spectroscopy (EDX) and SEM (Scanning Electron Microscopy) analysis. Results support substantial equivalence of the BoneTrust® Mini 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® Mini Implant System is substantially equivalent to the predicate devices.