April 13, 2023

PointNix Co., Ltd
% BoKyeong Kim
Senior Researcher
GMS Consulting
4th Floor, Digital Cube, 34, Sangamsan-ro
Seoul, Mapo-gu 03909
REPUBLIC OF KOREA

Re: K222738
Trade/Device Name: Point implant system
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 17, 2023
Received: March 17, 2023

Dear BoKyeong Kim:

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222738

Device Name
Point implant system

Indications for Use *(Describe)*
Point implant system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

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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PointNix Co., Ltd.
B1 and 3F, 7, Hyoyeol-ro, Buk-gu, Busan, KOREA

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

April 05, 2023

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: PointNix Co., Ltd
  - Address: B1 and 3F, 7, Hyoyeol-ro, Buk-gu, Busan, KOREA
- Contact Name: Chang Nam Lee / Manager
  - Telephone No.: +82-51-363-3201
  - Email Address: changnamgu@pointnix.com
- Name of Manufacturer: PointNix Co., Ltd
  - Address: B1 and 3F, 7, Hyoyeol-ro, Buk-gu, Busan, KOREA

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

K no.	K222738
Product Name	Dental implant system
Model Name	Point implant system
Device Classification Name	Endosseous dental implant
Regulation Number	872.3640
Classification Product Code	DZE
Subsequent Product Code	NHA
Device Class	2
510k Review Panel	Dental

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate Device #1

- 510(k) Number: K121995
- Applicant: OSSTEM Implant Co., Ltd.
- Classification Name: Endosseous Dental Implant
- Proprietary Name: TS Fixture System
- Classification Product Code: DZE
- Regulation Number: 21 CFR 872.3630

Reference Device #2

- 510(k) Number: K153015
- Applicant: OSSTEM Implant Co., Ltd.
- Classification Name: Endosseous Dental Implant
- Proprietary Name: Transfer & Angled Abutment
- Classification Product Code: NHA
- Regulation Number: 21 CFR 872.3630

Reference Device #3

- 510(k) Number: K161689
- Applicant: OSSTEM Implant Co., Ltd.
- Classification Name: Endosseous Dental Implant
- Proprietary Name: OSSTEM Implant System-Abutment
- Classification Product Code: NHA
- Regulation Number: 21 CFR 872.3630

Reference Device #4

- 510(k) Number: K182091
- Applicant: OSSTEM Implant Co., Ltd.
- Classification Name: Endosseous Dental Implant
- Proprietary Name: Osstem Abutment System
- Classification Product Code: NHA
- Regulation Number: 21 CFR 872.3630

Reference Device #5

- 510(k) Number: K192436
- Applicant: Dentium Co., Ltd.
- Classification Name: Endosseous Dental Implant
- Proprietary Name: Healing Abutments and Cover Screw
- Classification Product Code: NHA

- Regulation Number: 21 CFR 872.3630

The predicate device has not been subject to a design-related recall

5. Description of the Device [21 CFR 807.92(a)(4)]

5.1. Overview

No.	Item	Contents
01	Applied Part	Oral
02	Contact duration	C(>30days)
03	Patient populations	Dental prosthetic patients

5.2. Fixture Information

Type		Dia(mm)	Length(mm)
POF, POF Q POF QNP	Mini	3.75	8.5 / 10.0 / 11.5 / 13.0
	Regular	4.05 / 4.55 / 5.05	7.0 / 8.5 / 10.0 / 11.5 / 13.0
		6.0 / 6.7	7.0 / 8.5 / 9.5 / 11.0 / 12.5

Type is classified according to the packaging method.

- POF: Ampoule packing
- POF Q: Quartz packing
- POF QNP: Quartz pin packing

5.3. Mount & Mount Screw information

Type		Dia(mm)	Length(mm)
Mount	Mini	2.08	9.6
	Regular	2.48	10.1
Mount Screw	Mini	1.5	16.5
	Regular	1.8	15.6

5.4. Abutment / Abutment screw Information

Type		Dia(mm)	Length(mm)
Cemented Abutment	Mini	4.5	9.2 / 10.2 / 11.2 / 12.2 / 13.2
	Regular	4.6	9.0 / 10.0 / 11.0 / 12.0 / 13.0
		5.0 / 6.0	7.5 / 8.5 / 9.0 / 9.5 / 10.0 / 10.5 / 11.0 11.5 / 12.0 / 12.5 / 13.0 / 13.5 / 14.5
		7.0	9.0 / 10.0 / 11.0 / 12.0 / 13.0
Abutment	Mini	1.56	10.2

screw	Regular	1.96	8.35
Healing Abutment	Mini	4.3 / 4.8	7.5 / 8.5 / 9.5 / 11.5
	Regular	4.3 / 4.8 / 5.3 / 6.3 / 7.3	8.5 / 9.5 / 10.5 / 12.5
Angled Abutment (17°)	Mini (A, B, Non-Hex)	4.5	12.57 / 14.57
	Regular	5.0	12.47 / 14.47
		6.0	12.39 / 14.39
Solid Abutment	Mini	4.0 / 4.6	10.0 / 11.0 / 11.5 / 12.5 / 13.0 /13.5 14.0 / 14.5 / 15.0 / 15.5 / 16.0 / 17.0
	Regular	4.0 / 4.6 / 5.0 / 6.0	10.4 / 11.4 / 11.9 / 12.4 / 12.9 / 13.4 13.9 / 14.4 / 14.9 / 15.4 / 15.9 /16.4 / 17.4
		7.0	11.9 / 12.9 / 13.9 / 14.9 / 15.9
Cover screw	Mini	3.1	4.7
		3.0	5.2
	Regular	3.6	5.9
Temporary Abutment	Mini (Hex, Non-Hex)	4.0	13.9 / 15.9
	Regular (Hex, Non-Hex)	4.5	13.7 / 15.7
Cap	None	4.0 / 4.6 / 5.0 6.0 / 7.0	5.3 / 7.3 / 8.8

5.5. Material composition

NO.	Model Name	Raw Material	Standard
1	Fixture	Unalloyed Titanium	ASTM F67
2	Healing Abutment	Unalloyed Titanium	ASTM F67
3	Cover Screw	Unalloyed Titanium	ASTM F67
4	Mount	Alloyed Titanium	ASTM F136
5	Mount screw	Alloyed Titanium	ASTM F136
6	Cemented Abutment	Unalloyed Titanium	ASTM F67
7	Abutment Screw	Alloyed Titanium	ASTM F136
8	Angled Abutment	Unalloyed Titanium	ASTM F67
9	Solid Abutment	Unalloyed Titanium	ASTM F67
10	Temporary Abutment	Unalloyed Titanium	ASTM F67
11	Cap	Polyoxymethylene	CAS No.:30846-29-8

6. Indications for Use [21 CFR 807.92(a)(5)]

Point implant system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of these devices compared to the predicate device which adversely affect safety or effectiveness. A table comparing the key features of the subject device and the predicate device is provided below table.

[Table. Comparison of Proposed Device to Predicate Device]

1) Fixture

	Proposed Device	Predicate Device #1	Note
K Number	K222738	K121995	
Manufacturer	PointNix Co., Ltd.	OSSTEM Implant Co., Ltd.	
Product Code	DZE	DZE	Same
Regulation Number	21CFR872.3640	21CFR872.3640	Same
510(k) Review Panel	Dental	Dental	Same
Indications for Use	Point implant system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	The TS Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Same
Design			Similar

	Proposed Device	Predicate Device #1	Note
Composition of material	Titanium Grade 4 (ASTM F67)	Titanium Grade 4 (ASTM F67)	Same
Connection	Internal Hex-connected Submerged Fixture Tapered body shape and straight body shape	Internal Hex-connected Submerged Fixture Tapered body shape and straight body shape	Same
Platform diameters	3.75~6.7mm	3.75~6.8mm	Similar
Fixture diameter	3.75~6.7mm	3.75~6.8mm	Similar
Length	7~13mm	7~15mm	Similar
Sterilization	Gamma sterilization	Gamma sterilization	Same
Modified surface	S.L.A	S.L.A	Same
Thread pitch	0.8	0.8	Same
Substantial Equivalence Discussion			
The diameter and length of proposed device is slightly different with predicate device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent.			

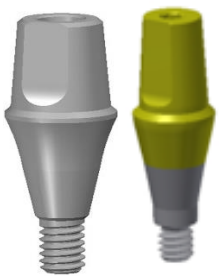
2) Abutment

<cemented abutment>

	Proposed Device	Reference Device #2	Note
K Number	K222738	K153015	
Manufacturer	PointNix Co., Ltd.	OSSTEM Implant Co., Ltd.	
Product Code	NHA	NHA	Same
Regulation Number	21CFR872.3640	21CFR872.3640	Same
510(k) Review Panel	Dental	Dental	same
Indications for Use	Point implant system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Transfer &Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	Similar
Design			Similar

	Proposed Device	Reference Device #2	Note
Composition of material	Titanium	Titanium	Same
Diameters	4.0, 4.6, 5.0, 6.0, 7.0mm	4.0 4.6, 5.0, 6.0, 7.0 mm	Same
Gingiva height	1.0, 2.0, 3.0, 4.0, 5.0mm	1.0, 2.0, 3.0, 4.0, 5.0mm	Same
Angulation	-	-	It is straight type.
Surface treatment	Machine, TiN-Coating	TiN-Coating	Similar
Sterilization	End user sterilization	End user sterilization	Same
Substantial Equivalence Discussion			
The diameter and length of proposed device is slightly different with predicate device. However, it does not affect device's fundamental functions and safety. Although there is a difference in surface treatment, biocompatibility tests were performed for our device, and there was no safety problem. Therefore, it is substantial equivalent.			

<solid abutment>

	Proposed Device	Reference Device#3	Note
K Number	K222738	K161689	
Manufacturer	PointNix Co., Ltd.	OSSTEM Implant Co., Ltd.	
Product Code	NHA	NHA	Same
Regulation Number	21CFR872.3640	21CFR872.3640	Same
510(k) Review Panel	Dental	Dental	Same
Indications for Use	Point implant system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Rigid Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	Similar
Design			Similar
Composition of material	Titanium	Titanium	Same
Diameters	4.0, 4.6, 5.0, 6.0, 7.0mm	4.0, 4.6, 5.0, 6.0, 7.0mm	Same
Gingiva height	0.8, 1.8, 2.8, 3.8, 4.8mm	1.0, 2.0, 3.0, 4.0, 5.0mm	Similar

	Proposed Device	Reference Device#3	Note
Angulation	-	-	It is straight type abutment
Surface treatment	Machine, TiN-Coating	TiN-Coating	Similar
Sterilization	End user sterilization	End user sterilization	Same
Substantial Equivalence Discussion			
The diameter and length of proposed device is slightly different with predicate device. However, it does not affect device's fundamental functions and safety. Although there is a difference in surface treatment, biocompatibility tests were performed for our device, and there was no safety problem. Therefore, it is substantial equivalent.			

<angled abutment>

	Proposed Device	Reference Device #2	Note
K Number	K222738	K153015	
Manufacturer	PointNix Co., Ltd.	OSSTEM Implant Co., Ltd.	
Product Code	NHA	NHA	Same
Regulation Number	21CFR872.3640	21CFR872.3640	Same
510(k) Review Panel	Dental	Dental	Same
Indications for Use	Point implant system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Transfer &Angled Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	Similar
Design			Similar
Composition of material	Titanium	Titanium	same
Diameters	4.5, 5.0, 6.0mm	4.0, 4.3, 4.5, 5.0, 5.5, 6.0 mm	Similar
Gingiva height	2.0, 4.0mm	2.0, 4.0mm	same
Angulation	17°	17°	Same
Surface treatment	Machine, TiN-Coating	TiN-Coating	Similar
Sterilization	End user sterilization	End user sterilization	Same
Substantial Equivalence Discussion			

	Proposed Device	Reference Device #2	Note
The diameter and length of proposed device is slightly different with predicate device. However, it does not affect device's fundamental functions and safety. Although there is a difference in surface treatment, biocompatibility tests were performed for our device, and there was no safety problem. Therefore, it is substantial equivalent.			

<temporary abutment>

	Proposed Device	Reference Device #4	Note
K Number	K222738	K182091	
Manufacturer	PointNix Co., Ltd.	OSSTEM Implant Co., Ltd.	
Product Code	NHA	NHA	Same
Regulation Number	21CFR872.3640	21CFR872.3640	Same
510(k) Review Panel	Dental	Dental	Same
Indications for Use	Point implant system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Temporary Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or over-dentures.	Similar
Design			Similar
Composition of material	Titanium	Titanium	Same
Diameters	4.0, 4.5mm	4.0, 4.5mm	Same
Gingiva height	11, 13mm	11, 13mm	Same
Angulation	-	-	Same It is straight type abutment
Surface treatment	Machine	Machine	Similar
Sterilization	End user sterilization	End user sterilization	Same
Substantial Equivalence Discussion			
The diameter and length of proposed device is slightly different with predicate device. However, it does not affect device's fundamental functions and safety. Although there is a difference in surface treatment, biocompatibility tests were performed for our device, and there was no safety problem. Therefore, it is substantial equivalent.			

<abutment screw>

	Proposed Device	Reference Device #3	Note
K Number	K222738	K161689	
Manufacturer	PointNix Co., Ltd.	OSSTEM Implant Co., Ltd.	
Product Code	NHA	NHA	Same
Regulation Number	21CFR872.3640	21CFR872.3640	Same
510(k) Review Panel	Dental	Dental	Same
Design			Similar
Composition of material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Same
Diameters	2.22, 2.33mm	2.0, 2.05, 2.2, 2.3, 2.5mm	Similar
Length	8.35, 10.2mm	3.35, 5.6, 7.5, 8.35, 9.6, 10.2mm	Similar
Surface treatment	Machine	WC Coating	Different
Sterilization	End user sterilization	End user sterilization	Same
Substantial Equivalence Discussion			
The diameter and length of proposed device is slightly different with predicate device. However, it does not affect device's fundamental functions and safety. Although there is a difference in surface treatment, Our device does not have surface coating. Therefore, it is substantial equivalent.			

<Cap>

	Proposed Device	Reference Device #3	Note
K Number	K222738	K161689	
Manufacturer	PointNix Co., Ltd.	OSSTEM Implant Co., Ltd.	
Product Code	NHA	NHA	Same
Regulation Number	21CFR872.3640	21CFR872.3640	Same
510(k) Review Panel	Dental	Dental	Same
Design			Similar
Composition of material	Polyoxumethylene (CAS No. 30846-29-8)	Polycarbonate (CAS No. 111211-39-3)	Different
Diameters	4.0, 4.6, 5.0, 6.0, 7.0mm	3.5mm	Different
Length	5.8, 7.3, 8.8mm	9.35, 9.75, 10.35,	Different

	Proposed Device	Reference Device #3	Note
		10.75,11.35, 11.75, 12.35, 12.75, 13.35, 13.75, 14.35, 14.75mm	
Surface treatment	-	-	Same
Sterilization	End user sterilization	End user sterilization	Same
Substantial Equivalence Discussion			
The diameter and length of proposed device is slightly different with predicate device. However, it does not affect device's fundamental functions and safety. Although there are differences in the raw materials, the cap is contact temporarily for patients and is a commonly used safe material. Therefore, it is substantial equivalent.			

<healing abutment>

	Proposed Device	Reference Device #5	Note
K Number	K222738	K192436	
Manufacturer	PointNix Co., Ltd.	Dentium Co., Ltd.	
Product Code	NHA	NHA	Same
Regulation Number	21CFR872.3640	21 CFR 872.3630	Same
510(k) Review Panel	Dental	Dental	Same
Indications for Use	Point implant system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Dentium prosthetics are intended for use as an aid in prosthetic rehabilitation.	Similar
Design			Similar
Composition of material	Titanium	Titanium	Same
Diameters	4.3, 4.8, 5.3, 6.3, 7.3mm	4.04, 4.1, 4.14, 4.2, 4.5, 4.54, 4.64, 4.7, 5.5, 5.54, 5.64, 5.75, 6.5, 6.54, 6.64, 6.75, 7.64, 8.64, 9.64mm	Similar
Gingiva height	8.5, 9.5, 10.5, 12.5mm	8.7, 10.91, 10.93, 11.04, 11.15, 12.41, 12.44, 12.55, 12.65, 12.66,	Similar

	Proposed Device	Reference Device #5	Note
		14.42, 14.44, 14.55, 14.66mm	
Angulation	-	-	
Surface treatment	Machined	Machine	Same
Sterilization	gamma sterilization	gamma sterilization	Same
Substantial Equivalence Discussion			
The diameter and length of proposed device is slightly different with predicate device. However, it does not affect device's fundamental functions and safety. Therefore, it is substantial equivalent.			

<cover screw>

	Proposed Device	Reference Device #5	Note
K Number	K222738	K192436	
Manufacturer	PointNix Co., Ltd.	Dentium Co., Ltd.	
Product Code	NHA	NHA	Same
Regulation Number	21CFR872.3640	21 CFR 872.3630	Same
510(k) Review Panel	Dental	Dental	Same
Indications for Use	Point implant system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple units restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.	Dentium prosthetics are intended for use as an aid in prosthetic rehabilitation.	Similar
Design			Similar
Composition of material	Titanium	Titanium	Same
Diameters	3.0, 3.1, 3.6mm	3.1, 3.5mm	Similar
Length	4.7, 5.2, 5.9mm	4.7, 5.7mm	Similar
Surface treatment	Machine	Machine	Same
Sterilization	gamma sterilization	gamma sterilization	Same
Substantial Equivalence Discussion			
The diameter and length of proposed device is slightly different with predicate device. However, it			

	Proposed Device	Reference Device #5	Note
does not affect device's fundamental functions and safety. Therefore, it is substantial equivalent.			

There are no significant differences between the point implant system and the predicate device that would be adversely affect the use of the product. It is substantially equivalent to these devices in indications for use, design, material, connection, sterilization, surface treatment, thread pitch. It is similar but slight differences on dimensions with compared with predicate device. However, it does not affect device's fundamental functions and safety. And, although there are differences in the raw materials, the cap is contact temporarily for patients and is a commonly used safe material. In the case of Healing Abutment and Cover Screw, gamma sterilization has the same sterilization method as products of the same class, but our products are different from those of the same class in that steam sterilization (user sterilization) is also possible. But the safety was confirmed by verifying moist heat sterilization of the abutment that had undergone the same process with the same raw material.

8. Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

The following data were provided in support of the substantial equivalence determination:

1) Bio-compatibility

Bio-compatibility test is performed according to below:

- FDA Guidance document Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-3 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
- ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin sensitization
- ISO 10993-11 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

2) Performance test

Non-clinical tests followed the recommendations in the "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant abutments".

- Fatigue Testing according to ISO 14801:2016 was performed on the subject device under the worst-case scenario and its result is strong enough to achieve their intended use.
- The proposed device will not be marketed as non-pyrogenic. During routine production, the method used to determine that the proposed sterile device meet the established pyrogen limit is the Limulus amebocyte lysate (LAL) test according to the USP Bacteria Endotoxins Test.

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

The surface modification information with SLA (Sandblasted Large grit and Acid-etched) surface treatment under the worst-case construction.

Below performance testing and information have been provided for implant fixture packaging:

- Usability Evaluation Testing (A usability evaluation for aseptic presentation of the subject device, in line with ISO 11607-1:2019 and the recommendations of the FDA guidance document, "Applying Human Factors and Usability Engineering to Medical Devices.")
- Low and high magnification images at various degrees of rotation following the removal from the packaging (Evaluation of the broken tip at various degrees rotation at a high magnification and low magnification for damage after removal from the packaging and disconnection of the fixture jig)
- Quality System (QS) plan including the method and frequency of acceptance activities to ensure that the devices conform with product specifications with packaging design.

3) Validation

[Gamma sterilization]

The gamma sterilization according to ISO 11137-1 and ISO 11137-2, demonstrating a sterility assurance level (SAL) of 10^{-6} accelerated aging study demonstrating a shelf life of 5 years for fixture, 8 years for healing abutment.

[User sterilization]

The steam sterilization validation according to ANSI/AAMI ST79, ANSI/AAMI ST8, ISO 17665 ISO 17665-1 and ISO 17665-2, demonstrating a sterility assurance level (SAL) of 10^{-6}.

4) MR Environment

MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., Woods, Terry O., Jana G. Delfino, and Sunder Rajan."Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system to include all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The rationale addressed parameters per the FDA Guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment", including magnetically induced displacement force and torque."

9. Clinical Test Summary [21 CFR 807.92(b)(2)]

Clinical testing is not included in this submission.

10. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between proposed device and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

11. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the Point implant system is substantially equivalent in safety and effectiveness to the predicate device as described herein.