Synoross DBA OsseOne
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

May 8, 2025

Re: K233271
Trade/Device Name: OsseOne Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 8, 2025
Received: April 9, 2025

Dear Angela Blackwell:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233271

Device Name
OsseOne Dental Implant System

Indications for Use *(Describe)*
The OsseOne Dental Implant System implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. OsseOne Dental implants are intended for single or multiple unit restorations on splinted or non-splinted applications. OsseOne Dental implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.

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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510k Summary
May 6, 2025
OsseOne Dental Implant System
K233271

Name and address: OsseOne
330 N. Central Ave
Glendale, CA 91203
Contact Person: Gene Shapiro
Phone Number: (310) 980-3632
Email: gene.shapiro@gmail.com
Name of device: OsseOne Dental Implant System
Classification Name: Endosseous dental implants
CFR: 21 CFR 872.3640
Primary Product Code: DZE
Secondary Product Code: NHA
Regulatory Classification: II

Submission Contact:
Angela Blackwell
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Device Description: The OsseOne Dental Implant System contains 1 design of internal hex implant and a multipurpose indexed hex abutment as described below as well as 3 designs of conical implant with NP and RP platforms and abutments corresponding to both platforms. All devices are made from ASTM F136 Ti-6AL-4V ELI unless otherwise noted. The implants have a grit blasted and acid etched surface. Conical abutments need to match the implant platform of narrow or regular. No abutments are intended to be modified by the user other than the multipurpose indexed abutments & tapered multipurpose abutments which can be reduced in height to a minimum of 6mm above the platform. Multipurpose indexed abutments & tapered multi-purpose abutments are not intended for angular correction and are not intended to be cast.

OsseoMax Hex implants are tapered internal hex implants with evenly spaced large threads the length of the implant. OsseoMax Hex comes in 4.6, and 5.4 mm diameter with lengths of 8, 10mm. OsseoMax Hex are only restored using hex ball attachments or Denture Lock hex cleared in K182293.

Tapered Multipurpose Indexed Hex Abutments have a 3.75mm platform diameter with a total height of 10.98mm. Height above the platform is 7.58mm. Tapered Multipurpose Indexed Hex Abutments are to be used with internal hex implant designs cleared in K182293 and are not to be used with OsseoMax Hex.

OsseoCone implants are slightly tapered conical implants with evenly spaced sharp edge threads with microthreads in between them as well as microgrooves in the collar. OsseoCone comes in NP (3.5mm), and RP (4.3, 5.0, and 5.5mm) in lengths of 8.5, 10, 11.5, 13 and 15mm.

OsseoCone Plus implants are very slightly tapered conical implants with more tightly spaced flat edge threads at the top and wider spaced sharp edge threads in the lower tapered section. OsseoCone Plus comes in 3.5 (NP), 4.3 (RP), 5.0 (RP) and, 5.5 (RP) mm diameter with lengths of 8, 10, 11.5, 13, and 16 mm (no 5.5 x 16mm).

OsseoMax Conical implants tapered conical implants with evenly spaced large threads the length of the implant. OsseoMax Conical comes in 4.6 and 5.4 RP diameter with lengths of 8, 10mm. OsseoMax Conical are only restored using Conical ball attachments or Conical Denture Lock.

Conical healing caps come in NP and RP (3.75 and 4.5 mm diameter) with cuff heights (also height above gingiva) of 2,3,4,5 mm. Total heights are 7.32, 8.32, 9.32, 20.32 mm and 7.47, 8.47, 9.47, 10.47mm. NP and RP conical cover screws are also available. A healing cap for multi-units is available.

Conical straight abutments in 4.5mm diameter come in NP and RP with heights above gingiva of 7.7, 10.7 and 6.1, 8.3mm. Total heights are 11.85, 15.9mm and 10.6, 13mm.

Conical anatomic abutments in 4.5mm diameter come in NP and RP with gingival heights of 1,2,3 mm. Height above the platform is 7.5mm. Total heights are 11.8, 12.6, 13.6mm for both NP and RP versions.

Conical angled anatomic abutments in 5mm diameter come in 15° and 25° NP with shoulder cuff heights of 1,2,3 mm and total heights of 10.7, 12.2, 13.7 mm. Height above platform is 7.6mm.

Conical angled anatomic abutments in 5mm diameter come in 15° and 25° RP with shoulder cuff heights of 1,2,3,4 mm and total heights of 11, 12, 13, 14 mm. Height above platform is 8.4mm.

Multipurpose Indexed Conical abutment comes in NP, RP, and RP Wide with platform diameters of 4.2, 4.2 and 4.7 mm Total heights are 11.69, 11.33 and 11.33 mm. Height above platform is 8.29, 7.93, 7.93mm. Multipurpose Indexed Conical abutments are to be used with the conical implants listed above but are not to be used with OsseoMax Conical Implants.

Conical ball attachments come in 3.5mm diameter for NP and 5.0mm diameter for RP with cuff heights of 1,2,3,4,5,6 mm. Total heights are 9.5, 10.5, 11.5, 12.5, 13.5, 14.5mm and 9.45, 10.45, 11.45, 12.45, 13.45, 14.45mm. Height above the platform is 3.47, 4.47, 5.47, 6.47, 7.47, 8.47mm and 4, 5, 6, 7, 8, 9mm.The ball attachments snap into a stainless steel housing which has a polyamide or polyether retention cap. The Retention Caps come in the colors yellow, pink and clear which represent 0.5, 0.9,

and 1.3 kg retention levels. The retention caps allow implants to be within 14° of vertical and still snap into place. The housing and retention caps were cleared in K182293.

Conical Denture Lock attachments come in 3.5mm diameter for NP and 5.0mm diameter for RP with cuff heights of 1,2,3,4 mm. Total heights are 8.95, 9.95, 10.95, 11.95mm and 8.7, 9.7, 10.7, 11.7mm. Height above the gingiva is 2.3, 3.3, 4.3, 5.3mm. The Denture Lock attachments snap into a Ti6AL4V ELI housing which has a polyamide, polyether or polyoxymethylene retention cap. The Retention Caps come in the colors yellow, pink, clear, purple which represent 0.6, 0.8, 1.0, 1.5 kg retention levels. The retention caps allow implants to be within 20° of vertical and still snap into place. The housing and retention caps were cleared in K182293.

Conical straight multi-units in NP and RP are 4.8mm in diameter with cuff heights of 1,2,3,4,5 mm. Height above platform is 3.6, 4.6, 5.6, 6.6, 7.6mm. Total heights are 9.1, 10.1, 11.1, 12.1, 13.1mm and 9.25, 10.25, 11.25, 12.25, 13.25mm.

Conical NP and RP Angled Multi-Units are 4.8mm in diameter and come in 17° and 30° with cuff heights of 1, or 2 mm. Cone height above platform 2.15mm. NP total heights are 6.35, 7.35mm and 6.85, 7.85mm. RP total heights are 6.75, 7.11mm and 7.15, 8.15mm.

Conical abutment screws in NP & RP are used with conical abutments including angled multi-units.

Indications for Use:
The OsseOne Dental Implant System implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. OsseOne Dental implants are intended for single or multiple unit restorations on splinted or non-splinted applications. OsseOne Dental implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.

Testing Summary: Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments and implants are strong enough for their intended use. Biocompatibility testing from K182293 is being leveraged for the abutments and implants in this submission. Cytotoxicity testing according to ISO 10993 was done on both implants and abutments. Skin sensitization testing according to ISO 10993-10:2021 was conducted on implants. Irritation testing according to ISO 10993-23:2021 was conducted on implants. Steam sterilization validation was conducted according to ISO 17665-1. Tests relating to gamma validation, packaging and shelf life from K182293 are leveraged for the tests listed. Bacterial endotoxin testing was conducted according to ANSI/AAMI ST72:2019 and USP <161>. Gamma irradiation validation was conducted according to ISO 11137-2. Package testing was conducted according to ASTM D999-08, ASTM F3039-13, and ASTM D5276-98(2009) and then shelf life testing was conducted according to ASTM F1929-12, and ASTM F1980-07. Testing of the modified surface included testing for organic carbon, hydrocarbons, and SEM/EDX. All were within the limits based on relevant standards set in the cleaning validation protocol.

MR Environment Condition

Non-clinical worst-case MRI review was performed to evaluate the metallic OsseOne Dental Implant System devices in the MRI environment using scientific rationale and published literature (e.g., 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 including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. 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.

Primary Predicate Device: OsseoPlus and OsseoLock from OsseOne Dental Implant Systems K182293
Reference Predicates: TOV Dental Implant System K240837 Surgikor Dental Implant System K182615

Substantial Equivalence:
The OsseOne Dental Implant System is substantially equivalent to the previous version of the OsseOne Dental Implant System in indications for use, and materials including surface treatment and substantially equivalent to TOV Dental Implant System and Surgikor Dental Implant System in design, and fatigue performance. Slight differences in implant and abutment design between the subject devices and the predicate devices were addressed by showing both had adequate fatigue performance.

Company & Device Name	OsseOne Dental Implant System Subject Device	OsseoPlus and OsseoLock from OsseOneDental Implant System K182293 Predicate Device	Surgikor's Dental Implant System K182615 Reference Device	TOV Dental Implant System K240837 Reference Device
Indications for Use	The OsseOne Dental Implant System implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. OsseOne Dental implants are intended for	OsseOne Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. OsseOne implants are intended for single or multiple	Surgikor's Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Dental Implant System is indicated also for	The TOV Dental Implant System are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Implanet implants are

	single or multiple unit restorations on splinted or non-splinted applications. OsseOne Dental implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.	unit restorations on splinted or non-splinted applications. OsseoPlus and OsseoLock are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period. OsseoLock 3.3 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.3 implants adjacent to one another.	immediate loading when good primary stability is achieved and with appropriate occlusal loading. The 7mm implants are intended to be used in the molar region.	intended for single or multiple unit restorations on splinted or non-splinted applications. Maer, Ragil and TCX are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period. Ragil 3.3 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.3 implants adjacent to one another.
Implant Diameters	OsseoCone NP 3.5mm RP 4.3, 5.0, 5.5 mm OsseoCone Plus NP 3.5mm RP 4.3, 5.0, 5.5 mm OsseoMax Conical 3.5 NP, 4.2 RP and Hex 3.5, 4.2 mm	OsseoLock 3.3, 3.75, 4.2, 5.0, 6.0mm OsseoPlus 3.5, 3.75, 4.2, 5.0, 6.0mm	Fixation Narrow Platform 3.0mm Fixation Regular Platform 3.5, 3.9mm Fixation Wide Platform 4.3, 5.0mm Solution5 Narrow Platform 3.25mm	Maer 3.5, 3.75, 4.2, 5.0, 6.0 mm Ragil 3.3, 3.75, 4.2, 5.0, 6.0 mm TCX 3.5, 4.3, 5.0 mm NP = 3.5 RP = 4.3, 5.0

			Solution5 Regular Platform 3.5, 4.0mm Solution5 Wide Platform 4.5, 5.0, 5.5, 6.0mm Solution2 3.25mm	
Implant Lengths	OsseoCone 8.5, 10, 11.5, 13, 15mm OsseoCone Plus 8.5, 10, 11.5, 13, 16mm (no 5.5 x 16mm) OsseoMax Conical and Hex 8, 10 mm	8, 10, 11.5, 13, 16 (OsseoLock 5.0 and 6.0 not in 16mm)	Fixation Narrow Platform 10, 11.5, 13, 15mm Fixation Regular Platform 8.5, 10, 11.5, 13, 15, 18mm Fixation Wide Platform 8.5, 10, 11.5, 13, 15, 18mm Solution5 Narrow Platform 10,11.5, 13, 15mm Solution5 Regular Platform 7.0 (4.0 diameter only), 8.5, 10, 11.5, 13, 15mm Solution5 Wide Platform 7.0, 8.5, 10, 11.5, 13, 15mm Solution2 10, 11.5,13 16mm	Maer 8, 10, 11.5, 13,16mm (no 16mm in 6.0mm diameter) Ragil 8, 10, 11.5, 13, and 16mm (no 16mm in 5.0 or 6.0mm diameter) TCX 8, 10, 11.5, 13,16mm
Material of devices included in the submission	Ti-6AL-4V ELI	Ti-6AL-4V ELI	Ti-6AL-4V ELI	Ti-6AL-4V ELI
Interface type/shape	Internal hex, conical	Internal hex	conical	Internal hex, conical
ISO 14801 Fatigue Testing	Sufficient run out load for their intended use	Sufficient run out load for their intended use	Sufficient run out load for their intended use	Sufficient run out load for their intended use

Surface Treatment	SLA	SLA	HA blasted and double acid etched	SLA
Post Surface Treatment Cleanliness Demonstrated	Yes	Yes	Yes	Yes

	OsseOne Dental Implant System (This submission)	OsseoPlus and OsseoLock from OsseOne Dental Implant System K182293	Surgikor Dental Implant System K182615	TOV Dental Implant System K240837
Cover screw	Cover screw for NP and RP	Cover Screw for IH	Cover screws NP and RP	Cover screws for NP and RP
Multi-Unit Abutments in NP and RP	4.8 mm diameter multi-units in NP and RP with cuff heights of 1,2,3,4,5mm. Height above platform is 3.6, 4.6, 5.6, 6.6, 7.6mm. Total heights are 9.1, 10.1, 11.1, 12.1, 13.1mm and 9.25, 10.25, 11.25, 12.25, 13.25mm.	4.5 mm multi-unit abutments in heights of 1,2,3 and 4 mm	5.00 mm multi-unit abutments in heights of 1,2,3 and 4 mm	4.8 mm diameter multi-units in NP and RP with cuff heights of 1,2,3,4,5mm. Height above platform is 3.6, 4.6, 5.6, 6.6, 7.6mm. Total heights are 9.1, 10.1, 11.1, 12.1, 13.1mm and 9.25, 10.25, 11.25, 12.25, 13.25mm.
17° and 30° Angled Multi-Unit Abutments NP and RP	17° and 30° Angled Multi-Unit Abutments NP and RP with platform heights of 1,2 mm Cone height above platform 2.15mm. NP total heights are 6.35, 7.35mm and 6.85, 7.85mm. RP total heights are 6.75, 7.11mm and 7.15, 8.15mm.	17° and 30° overdenture abutments in heights of 1,2, and 3 mm	18° and 30° Multi-unit abutments in platform heights of 1,2,3 and 4 mm	17° and 30° Angled Multi-Unit Abutments NP and RP with platform heights of 1,2 mm Cone height above platform 2.15mm. NP total heights are 6.35, 7.35mm and 6.85, 7.85mm. RP total heights are 6.75, 7.11mm and 7.15, 8.15mm.

Locator Abutments with metal housing and retention cap allowing 20° divergence of the implants	Conical Denture Lock attachments NP and RP (3.9mm) Cuff heights of 1, 2, 3, 4, mm Total heights are 8.95, 9.95, 10.95, 11.95mm and 8.7, 9.7, 10.7, 11.7mm. Height above the gingiva is 2.3, 3.3, 4.3, 5.3mm. Ti6Al4V ELI housing Polyamide, polyether or polyoxymethylene retention cap with retention levels from 0.6to 1.5 kg Housing and retention cap cleared in K182293.	Denture Lock attachments 3.85mm diameter in cuff heights of 1,2,3,4, 5, and 6 mm Ti6AL4V ELI housing Polyamide, polyether or polyoxymethylene retention cap with retention levels from 0.6to 1.5 kg	3.85mm diameter Locator abutments in heights of 1,2,3,4,5, and 6mm Ti6AL4V ELI housing Polyamide, polyether or polyoxymethylene retention cap with retention levels from 0.6to 1.5 kg	Conical Retentor attachments NP and RP (3.9mm) Cuff heights of 1, 2, 3, 4, mm Total heights are 8.95, 9.95, 10.95, 11.95mm and 8.7, 9.7, 10.7, 11.7mm. Height above the gingiva is 2.3, 3.3, 4.3, 5.3mm. Ti6Al4V ELI housing Polyamide, polyether or polyoxymethylene retention cap with retention levels from 0.6to 1.5 kg Housing and retention cap.
Ball attachments with metal housing and retention cap allowing 14° divergence of the implants	Conical ball attachments NP (3.5mm diameter) and RP (5.0mm diameter) Cuff heights of 1,2,3,4,5,6 mm for NP and RP Total heights are 9.5, 10.5, 11.5, 12.5, 13.5, 14.5mm and 9.45, 10.45, 11.45, 12.45, 13.45, 14.45mm. Height above the platform is 3.47, 4.47, 5.47, 6.47, 7.47, 8.47mm and 4, 5, 6, 7, 8, 9mm.	4.00 mm Ball attachments in platform heights of 2,3,4,5, and 6mm Stainless steel 316 housing Polyamide or polyether retention cap with retention levels from 0.5 to 1.3 kg	4.1 mm Ball attachments in heights of 1,2,3,4,5, and 6mm Polyamide or polyether retention cap with retention levels from 0.5 to 2.7 kg	Conical ball attachments NP (3.5mm diameter) and RP (5.0mm diameter) Cuff heights of 1,2,3,4,5,6 mm for NP and RP Total heights are 9.5, 10.5, 11.5, 12.5, 13.5, 14.5mm and 9.45, 10.45, 11.45, 12.45, 13.45, 14.45mm. Height above the platform is 3.47, 4.47, 5.47, 6.47, 7.47, 8.47mm and 4, 5, 6, 7, 8, 9mm.

	Stainless steel 316 housing Polyamide or polyether retention cap with retention levels from 0.5 to 1.3 kg Housing and retention caps cleared in K182293.			Stainless steel 316 housing Polyamide or polyether retention cap with retention levels from 0.5 to 1.3 kg Housing and retention caps.
Healing Caps 3.8mm	3.75 diameter NP healing cap in 2,3,4,5 mm (also height above gingiva) cuff heights Total heights are 7.32, 8.32, 9.32, 20.32 mm..	3.8mm diameter Healing Cap in 3,4,5,6,7 mm platform height		3.75 diameter NP healing cap in 2,3,4,5 mm (also height above gingiva) cuff heights Total heights are 7.32, 8.32, 9.32, 20.32 mm..
Healing Caps 4.5 diameter standard	4.5 mm diameter RP healing cap with cuff heights 2,3,4,5 mm (also height above gingiva). Total heights are 7.47, 8.47, 9.47, 10.47mm.	4.5mm diameter Healing cap in 2,3,4,5,6, and 7mm platform height	4.5mm diameter Healing cap in 2,3,4,5,6mm platform height	4.5 mm diameter RP healing cap with cuff heights 2,3,4,5 mm (also height above gingiva). Total heights are 7.47, 8.47, 9.47, 10.47mm.
Standard Titanium Abutment	NP and RP 4.5mm diameter with heights above gingiva of 7.7, 10.7 and 6.1, 8.3mm. Total heights are 11.85, 15.9mm and 10.6, 13mm.		4.9mm Non-shouldered Standard Titanium Abutment with heights of 5,7, 9, 12, and 15 mm	NP and RP 4.5mm diameter with heights above gingiva of 7.7, 10.7 and 6.1, 8.3mm. Total heights are 11.85, 15.9mm and 10.6, 13mm
Standard Shoulder Abutment	4.5 diameter NP, RP anatomic abutment with shoulder heights of 1,2,3 mm Height above the platform is	4.5mm diameter Standard Wide Shoulder Abutment with heights of 1,2,3,4 mm and total heights of 10.9,	4.3mm diameter Standard Wide Shoulder Abutment with heights of 1,2,3, and 4mm and total heights of	4.5 diameter NP, RP anatomic abutment with shoulder heights of 1,2,3 mm Height above the platform is 7.5mm. Total heights are

	7.5mm. Total heights are 11.8, 12.6, 13.6mm for both NP and RP versions.	11.9, 12.9, 13.9 mm 5.4mm diameter Standard Wide shoulder abutment with shoulder heights of 1.2.3 mm and total heights of 10.7, 11.7 and 12.7mm	9.5, 10.5, 11.5, 12.5 mm 6.9mm diameter wide emergence abutment total heights of 5,7,9,12,15 mm	11.8, 12.6, 13.6mm for both NP and RP versions.
Shouldered Standard 15° Abutment NP RP	Diameter 5.00 NP and RP 15° Angled Anatomic Abutment with cuff heights of 1,2,3 mm and total heights of 10.7, 12.2 and 13.7 mm & 11, 12, 13, 14 mm Height above platform is 7.6mm NP and 8.4mm RP.	3.75mm diameter 15° Angled Shoulder Abutment with cuff heights of 1,2,3 mm and height above low side of shoulder 8,9,10 mm	3.75mm diameter Anatomic Shouldered Standard 15° Abutment with collar heights of 1,2, or 3mm	Diameter 5.00 NP and RP 15° Angled Anatomic Abutment with cuff heights of 1,2,3 mm and total heights of 10.7, 12.2 and 13.7 mm & 11, 12, 13, 14 mm Height above platform is 7.6mm NP and 8.4mm RP.
Shouldered Standard 25° Abutment NP RP	Diameter 5.00 NP and RP 25° Angled Anatomic Abutment with cuff heights of 1,2,3 mm with total heights of 10.7, 12.2, and 13.7 mm & 11, 12, 13, 14 mm Height above platform is 7.6mm NP and 8.4mm RP.	3.75mm diameter 25° Angled Shoulder Abutment with cuff heights of 1,2,3 mm with heights above platform of 8.3,9.2,10.3 mm	3.75mm diameter Anatomic Shouldered Standard 25° Abutment with collar heights of 1,2, or 3mm	Diameter 5.00 NP and RP 25° Angled Anatomic Abutment with cuff heights of 1,2,3 mm with total heights of 10.7, 12.2, and 13.7 mm & 11, 12, 13, 14 mm Height above platform is 7.6mm NP and 8.4mm RP.
Indexed Shouldered Abutment	Tapered Multipurpose Indexed Hex Abutments IH with a diameter of		4.3mm diameter Standard Wide Shoulder Abutment with heights of 1,2,3,	

	3.75mm and total height of 10.98mm, with platform width 3.75mm and height above platform of 7.58mm. Multipurpose Indexed Conical Abutment NP, RP, RP Wide with diameters of 3.00, 3.4, 3.4mm and total heights of 11.69, 11.33, 11.33 mm. Platform width 4.2, 4.2, 4.7 mm Height above platform 8.29, 7.93, 7.93mm.		and 4mm and total heights of 9.5, 10.5, 11.5, 12.5 mm 6.9mm diameter wide emergence abutment total heights of 5,7,9,12,15 mm	

Conclusion:

OsseOne Dental Implant System is substantially equivalent to OsseoPlus and OsseoLock from the OsseOne Dental Implant System. They both have similar indications for use and are of the same material. The abutments, healing caps, and angled abutments are offered in similar designs and heights to TOV Dental Implant System. Surgikor Dental Implant System has conical connection implants like OsseOne Dental Implant System. Any abutment designs not found within the TOV Dental Implant System were found in the reference devices which have the same materials, similar indications for use and same conical connections as the OsseOne Dental Implant System. Performance testing demonstrates substantial equivalence to the identified predicate devices.