February 15, 2019

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

Re: K182293
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: January 8, 2019
Received: January 16, 2019

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 (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)*
K182293

Device Name
OsseOne Dental Implant System

Indications for Use *(Describe)*
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 patients esthetics and chewing function. OsseOne implants are intended for single or multiple 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.

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."

510k Summary
February 15, 2019
OsseOne Dental Implant System
K182293

Name and address: OsseOne
330 N Central Avenue
Glendale, CA 91203
Contact Person: Gene Shapiro
Phone Number: 818-242-3763
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

Device Description: OsseOne Dental Implant System is an internal hex implant system with two models of implant, OsseoLock which is a cylindrical implant and OsseoPlus which is a spiral implant. OsseoLock comes in 3.3, 3.7, 4.2, 5.0, and 6.0 diameter. OsseoPlus comes in diameters of 3.5, 3.75, 4.2, 5.0 and 6.0. The implants come in lengths of 8, 10, 11.5, 13 and 16. OsseoLock 5.0 and 6.0 diameter implants do not come in 16mm length. Both straight and angled abutments are available.

The implants have a grit blasted and acid etched surface. Standard abutments, standard narrow abutments, standard shoulder abutments, standard wide shoulder abutments, multi-unit abutments, denture lock abutments, overdenture abutments, angled overdenture abutments, ball attachments, healing caps (3.8, 4.6, 5.5, and 6.3 mm diameter), UCLA in 4.5mm diameter and standard 15° and 25° abutments are included in the system.

Indications for Use: 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 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.

Testing Summary: Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments are strong enough for their intended use. Both designs exhibited run out limits about the same or higher than other implant systems. Surface analysis according to the FDA guidance document was done. Sterilization validation was conducted on the implants according to ISO 11137-1 and ISO 11137-2. Abutment steam sterilization validation was done according to ISO 17665-1 and ISO 17665-2.

Package integrity testing and accelerated aging were conducted according to standards ASTM F1929-12, ASTM F 1980-07(2011), ASTM D 4332-13, ASTM D 999-08, ASTM D4169-09, ASTM D5276-98(2009) and ASTM F 3039-13. Materials used in the product meet ASTM F136. Endotoxin testing according to USP 161 was conducted. Cytotoxicity according to ISO 10993-5 was conducted on implants and abutments ready for final packaging.

Primary Predicate Device: SpiralTech Dental Implant System Ultimate Hex and Esi Hex K170372
Reference Devices: Zest Dental Solutions K083324 Locator Abutments and Cortex K090709

Substantial Equivalence:
OsseOne Dental Implant System is substantially equivalent to SpiralTech Dental Implant System in indications for use, materials, design, and fatigue performance. The indications for use are identical. The materials are the same and both systems have cytotoxicity testing which meets ISO 10993-5 to show the surfaces of the devices are not cytotoxic. The abutment designs are all very similar and in some cases practically identical. Any differences are minor ones of slight dimensional changes so do not change the substantial equivalence. Both systems have fatigue test according to ISO 14801 which cover all the models that demonstrate the systems are sufficiently strong for their common intended use. Both systems have gamma irradiation validation and endotoxin testing for the implants and steam sterilization validation for the abutments. Shelf life and package testing was conducted on both systems.

Implant System Comparison Table	OsseOne Dental Implant System OsseoLock OsseoPlus	SpiralTech Dental Implant System K170372 Ultimate Hex and ESi Hex
Diameter of Implants OsseoLock OsseoPlus	 3.3, 3.75, 4.2, 5.0, 6.0 3.5, 3.75, 4.2, 5.0, 6.0	 ESi Hex 3.3, 3.5, 4.3, 5.0, 6.0 Ultimate Hex 3.3, 3.5, 4.3, 5.0, 6.0
Implant Lengths	8, 10, 11.5, 13, 16 (OsseoLock 5.0 and 6.0 not in 16mm)	8, 10, 11, 13, 15
Surface Treatment	SLA	SLA or RBM
Sterilization of Implants	Provided sterile by gamma irradiation	Provided sterile by gamma irradiation
Sterilization of abutments	Provided non-sterile with instructions for user to sterilize them	Provided non-sterile with instructions for user to sterilize them
Connection	Internal Hex	Internal Hex
Spiral Implant Design	OsseoPlus	Ultimate Hex
Cylindrical Implant Design	OsseoLock	Esi Hex
ISO 14801 Fatigue Test	Run out limits for both designs are the same or higher than those of other implant systems	Run out limits are comparable to other implant systems.
Indications for Use	OsseOne Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to	The Spiraltech 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 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.	provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Spiraltech implants are intended for single or multiple unit restorations on splinted or non-splinted applications. The implants ESi Dynamic and Ultimate are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants [along with Premium and One Piece] can also be used for loading after a conventional healing period. Solo One Piece 3.0 and 3.3 implants, Ultimate (conical) 3.0 implants, and ESi (conical) 3.0 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 3.0 and/or 3.3 implants adjacent to one another.
Material	Ti6Al4V	Ti6Al4V

	OsseOne Dental Implant System	**SpiralTech Dental Implant System or Noted Reference Device**
Cover screw	Cover screw	Cover screw
Multi-Unit Abutments*	Multi-unit abutments in heights of 1,2,3 and 4 mm	Multi-unit abutments in heights of 1,2,3 and 4 mm
Ball attachments	Ball attachments in heights of 2,3,4,5, and 6mm	Ball attachments in heights of 1,2,3,4,5, and 6mm
Healing Caps 3.8 mm diameter	Healing Cap in 3,4,5,6,7 mm height	Healing Abutment in 2,3,4,5 and 6 mm height Cortex K090709 Healing abutment 7mm height

Healing Caps 4.6 mm diameter	Healing cap in 2,3,4,5,6, and 7mm height	Healing Abutment in 2,3,4,5, and 6 mm height Cortex K090709 Healing abutment 7mm height
Healing Caps 5.5 mm diameter	Healing cap in 2,3,4,5,6 and 7mm height	Healing Abutment in 2,3,4,5,and 6mm height Cortex K090709 Healing abutment 7mm height
Healing Caps 6.3 mm diameter	Healing Caps in 2,3,4 and 5 mm height	Cortex K090709 Healing Abutments in 2,3, 4 and 5 mm height
Standard Titanium Abutment	Standard Titanium Abutment with heights of 5,7,9, and 11 mm	Straight Titanium Abutment with height of 5,7,9 and 11 mm
Standard Narrow Abutment	Standard narrow abutment with heights of 5,7,9 and 11 mm	Straight narrow abutment with heights of 5, 7, 9, and 11mm
Standard Wide Abutment	Standard wide abutment with heights of 9 mm	Straight wide abutment with heights of 5,7,9,and 11 mm
Standard Shoulder Abutment	Standard shoulder abutment in heights of 1,2,3 and 4mm	Shoulder abutment in heights of 1,2,3 and 4mm
Standard Wide Shoulder Abutment	Standard Wide Shoulder Abutment with heights of 1,2,3 mm	Wide Shoulder Abutment with heights of 1,2 ,and 3mm
Standard 15° Abutment	Standard 15° Abutment with heights of 1,2,3 mm	Standard 15° Abutment with heights of 1,2,3 mm
Standard 25° Abutment	Standard 25° Abutment with heights of 1,2,3 mm	Standard 25° Abutment with heights of 1,2, and 3mm
Denture Lock Abutments *	Flat abutment in heights of 1,2,3,4,5,and 6 mm	Zest K083324 Locator abutment in heights of 1,2,3,4,5 and 6 mm
Standard Overdenture Abutment*	Overdenture abutment in 0.5, 1.5, and 2.5 mm heights	Cortex K090709 Clever click attachment with heights of 0,1,2,3,4,5 mm
Angled Overdenture Abutment*	15° and 25° overdenture abutments in heights of 1,2, and 3 mm and cover heights of 1,2 and 3 mm	17° and 30° Angled multi-unit abutment in heights of 1, 2 and 3 mm Cortex K090709 Multi-Unit angulated

		abutments 1,2, and 3 mm heights with cover heights in 1,2,3 mm
UCLA 4.5mm diameter	Castable abutments in diameters 4.5mm	Cortex K090709 Castable abutments 4.5mm diameter

***These models of abutments are not for single crown use.**

Conclusion:

OsseOne Dental Implant System is substantially equivalent to SpiralTech Dental Implant System. They both have the same indications for use, are of the same material, and have internal hex connections. The abutments, healing caps, and angled abutments are offered in similar designs and heights. Performance testing demonstrates substantial equivalence to the identified predicate devices.