Sites Medical, LLC
℅ Karen Warden
President
BackRoads Consulting
Po Box 566
Chesterland, Ohio 44026

July 14, 2021

Re: K202918
Trade/Device Name: OsteoSync™ Ti Dental Mesh
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: June 15, 2021
Received: June 16, 2021

Dear Karen Warden:

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,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental 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)*

Device Name
OsteoSync™ Ti Dental Mesh

Indications for Use *(Describe)*

The OsteoSync™ Ti Dental Mesh is intended for stabilization and support of bone grafts in dento-alveolar bony defect sites.

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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510(k) Summary

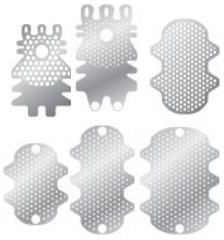
K202918

Date:	14 July 2021
Sponsor:	Sites Medical, LLC 5865 E State Road 14 Columbia City, IN 46725 Office: 260.625.3347
Sponsor Contact:	Greg Stalcup, President/CEO
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Name:	OsteoSync™ Ti Dental Mesh
Common Name:	Bone plate
Regulatory Class:	Class II
Regulation Name, Regulation, Product Code:	Bone plate, 872.4760, JEY
Device Description:	The OsteoSync™ Ti Dental Mesh is a system of dental membranes intended for permanent fixation in adults and designed to aid in the reconstruction and augmentation of the alveolar ridges of the maxilla and mandible. They are available in a variety of sizes and shapes and can be contoured to accommodate the individual anatomic and clinical circumstances of each patient. The implants are sold sterile.
Indications for Use:	The OsteoSync™ Ti Dental Mesh is intended for stabilization and support of bone grafts in dento-alveolar bony defect sites.
Materials:	The OsteoSync™ Ti Dental Mesh implants are manufactured from Grade 2 titanium as described by ASTM F67.
Primary Predicate:	Neo Titanium mesh and CTi-mem (neobiotech Co., Ltd – K111761)
Reference Devices:	SMARTbuilder System (OSSTEM Implant Co., Ltd – K130840), TraumaOne (Biomet Microfixation – the K081067), BoniPlus Dental G-Mesh System (MontJade Engineering Co., Ltd – K182759)
Non-clinical Testing:	Mechanical testing – worst case devices were evaluated per ASTM F564. Biocompatibility evaluation was leveraged from an FDA authorized master file. Sterilization validation was performed using gamma radiation and Method VDmax, in accordance with ISO 11137-1 and ISO 11137-2. Shelf life validation – sterile integrity was verified by visual, seal strength and seal integrity evaluations in accordance with ASTM F1886, ASTM F88, ASTM F1929 and ASTM F2096. Pyrogenicity – Bacterial endotoxin testing (specifically Limulus amebocyte lysate, LAL) was performed per ANSI/AAMI ST72. Preclinical animal studies in a canine model were relied upon to establish substantial equivalence.
Technological Characteristics:	The OsteoSync™ Ti Dental Mesh has many of the same technological characteristics as the predicate devices. These include anatomic location, material of manufacture, basic design, method of stabilization, sterile condition, variety of components offered and their general dimensional characteristics. The similarities and differences are provided in the following tables.

Overall system	Subject Device	Primary Predicate	Reference Devices		
Features🡻 System 🡺	OsteoSync™ Ti Dental Mesh	Neo Titanium mesh & CTi-mem	SMARTbuilder System	BoniPlus Dental G-Mesh System	TraumaOne
510(k)	K202918	K111761	K130840	K182759	K081067
Manufacturer:	Sites Medical LLC	neobiotech Co., Ltd.	OSSTEM Implant Co., Ltd.	MontJade Engineering Co., Ltd.	Biomet Microfixation, Inc.
Technological characteristics					
Basic design:	Dental mesh, various shapes	Dental mesh, various shapes	Dental mesh, various shapes	Dental mesh, various shapes	Dental mesh and plates, various shapes
Material of manufacture:	ASTM F67, Gr2	ASTM F67, Gr2	ASTM F67, Gr2	ASTM F67, Gr2	ASTM F67, Gr2 & Gr4
Method of stabilization:	Envelopment of bone graft with optional fastener attachment	Envelopment of bone graft with optional fastener attachment	Envelopment of bone graft with optional fastener attachment	Envelopment of bone graft with optional fastener attachment	Envelopment of bone graft with optional fastener attachment
Condition when used:	Sterile	Sterile	Sterile	Sterile	Sterile
System characteristics:					
Thickness:	0.41 to 0.52mm	0.07 & 0.085mm	0.1mm	0.1 to 0.3mm	0.2 to 0.6mm
Surface:	Smooth/smooth or smooth/rough sides	Smooth on both sides	Smooth on both sides	Smooth on both sides	Smooth on both sides
Pore Diameter:	0.43 to 0.66mm	0.4 to 0.8mm	0.6 to 1.0mm	Unknown	Unknown

Comments:

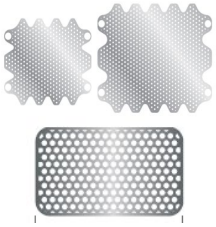
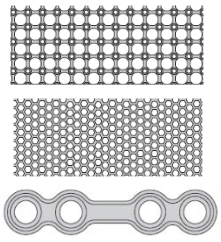
- The thickness of the subject device is greater than that of the Neo Titanium & CTi-mem and the SMARTbuilder systems but only fractionally larger than the largest BoniPlus implants. The thickness of the subject device is within the range offered by TraumaOne.
- The pore diameter size of the subject devices lies within those specified by the predicates.
- The surface texture of the subject device and cited predicates is smooth on both sides. However the subject device additionally offers a smooth gingival side / rough bone side option. The roughened side is intended to assist in securing the mesh to bone. Preclinical animal studies in a canine model provided support for this design. The preclinical animal studies were leveraged from an FDA-authorized master file.

Oval/round	Subject Device	Primary Predicate	Reference Device
Features↓ System →	OsteoSync™ Ti Dental Mesh	Neo Titanium mesh & CTi-mem	SMARTbuilder System
510(k)	K202918	K111761	K130840
Manufacturer:	Sites Medical LLC	neobiotech Co., Ltd.	OSSTEM Implant Co., Ltd.
Overall dimensions			
Insert diameter	2 to 6mm	2.5mm	~3mm (approximated)
Proximal width	5 to 12mm	4 to 15mm	4 to 12mm
Buccal width	4 to 8mm	8 to 15mm	7 to 12mm
Buccal length	5 to 8mm	6 to 20mm	3 to 9mm

Comments:

- The insert diameter of the subject device encompasses the range offered by the Neo Titanium & CTi-mem and the SMARTbuilder systems but extends to a larger range to broaden the system functionality for the end user by minimizing the need for manipulation of generic mesh.
- The buccal width of the subject device overlaps those provided in the Neo Titanium & CTi-mem and the SMARTbuilder systems but extends narrower to accommodate smaller defects such that the end user does not have to trim a generic mesh to obtain the implant form.

None of the dimensional differences in the individual mesh shapes raise new questions of substantial equivalence.

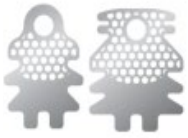
Posterior Graft	Subject Device	Primary Predicate	Reference Devices	
Features↓ System →	OsteoSync™ Ti Dental Mesh	Neo Titanium mesh & CTi-mem	BoniPlus Dental G-Mesh System	TraumaOne
510(k)	K202918	K111761	K182759	K081067
Manufacturer:	Sites Medical LLC	neobiotech Co., Ltd.	MontJade Engineering Co., Ltd.	Biomet Microfixation, Inc.
Overall dimensions				
Insert diameter	2 to 6mm	NA	NA	NA
Proximal width	15 to 34mm	12 to 35mm	25 to 60mm	80 to 85mm
Buccal width	10 to 20mm	12 to 35mm	17 to 60mm	80 to 85mm

Posterior Graft	Subject Device	Primary Predicate	Reference Devices	
Features↓ System →	OsteoSync™ Ti Dental Mesh	Neo Titanium mesh & CTi-mem	BoniPlus Dental G-Mesh System	TraumaOne
Buccal length (total)	15 to 24mm	15 to 30mm	NA	50 to 53mm

Comments:

- None of the predicate devices have a preformed insert diameter slot to accommodate a dental implant. However, all of the mesh shapes can be trimmed to form and perforated to accommodate a screw. The option broadens the functionality for the end user by minimizing the need for manipulation of generic mesh.
- The proximal width, buccal width and buccal length dimensions of the subject device lie within the range offered by the Neo Titanium & CTi-mem, BoniPlus G-mesh and the TraumaOne mesh systems.

None of the dimensional differences in the individual mesh shapes raise new questions of substantial equivalence.

Socket Graft	Subject Device	Primary Predicate	Reference Devices	
Features↓ System →	OsteoSync™ Ti Dental Mesh	Neo Titanium mesh & CTi-mem	SMARTbuilder System	BoniPlus Dental G-Mesh System
510(k)	K202918	K111761	K130840	K182759
Manufacturer:	Sites Medical LLC	neobiotech Co., Ltd.	OSSTEM Implant Co., Ltd.	MontJade Engineering Co., Ltd.
Overall dimensions				
Insert diameter	2 to 6mm	2.5mm	3.5-4mm	~3mm (approximated)
Proximal width	5 to 9.3mm	4 to 12mm	4 to 12mm	~5mm (approximated)
Buccal Length	10 to 13.5mm	6 to 10mm	7 & 9mm	9.5mm
Buccal Width	7 to 29mm	8 to 12mm	8 to 12mm	9mm

Comments:

- The insert diameter of the subject device encompasses the range offered by the Neo Titanium & CTi-mem and the SMARTbuilder systems but extends to a larger range to broaden the system functionality for the end user by minimizing the need for manipulation of generic mesh.
- The buccal width and length of the subject device overlap but extend longer than the range offered by the cited predicates to accommodate larger defects as necessary.
- The proximal width of the subject device lies within the range offered by the Neo Titanium & CTi-mem system.
- None of the dimensional differences in the individual mesh shapes raise new questions of substantial equivalence.

Conclusion:

The OsteoSync™ Ti Dental Mesh possesses the same intended use and technological characteristics as the predicate devices.

Nonclinical performance testing demonstrated substantial equivalence. Specifically,

- A biological risk assessment showed the submitted information and the preclinical animal studies provided in an FDA authorized master file mitigated risks with respect to biocompatibility.
- The sterilization validation achieved the predetermined acceptance criteria for a sterility assurance level (SAL) of 10^{-6}.
- The shelf-life validation met the predetermined acceptance criteria for a five year shelf-life.
- The bacterial endotoxin testing results met the predetermined pyrogen limit of 20EU/device.

Therefore the OsteoSync™ Ti Dental Mesh is substantially equivalent for its intended use.