July 29, 2020

MontJade Engineering Co., Ltd.
Yu Sheng Lin
R&D Engineer
No.2-1, Gongyequ 7th Road, Xitun District
Taichung City 40755
TAIWAN (R.O.C.)

Re: K182759
Trade/Device Name: "BoniPlus" Dental G-Mesh System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: July 27, 2020
Received: July 29, 2020

Dear Yu Sheng Lin:

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

Srinivas Nandkumar, Ph.D.
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)*
K182759

Device Name
"BoniPlus" Dental G-Mesh System

Indications for Use *(Describe)*
"BoniPlus" Dental G-Mesh System is the non-absorbable membrane that is made of titanium metal to stabilize and support 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

5.1 Type of Submission: Traditional

5.2 Date of Summary: 07/27/2020

5.3 Submitter:

Address:	MontJade Engineering Co., Ltd. No.22, Jingke Central 2nd Rd., Nantun Dist, Taichung City 408018, Taiwan
Phone:	+886-4-2350-6886
Fax:	+886-4-2350-8998
Representative:	Jiunn-Liang Chen, President

5.4 Identification of the Device:

Proprietary/Trade name:	"BoniPlus" Dental G-Mesh System
Primary Product Code:	JEY
Secondary Product Code:	DZL
Regulation Number:	872.4760
Regulation Description:	Bone plate
Review Panel:	Dental
Device Class:	II
Basis for the Submission:	New Device

5.5 Identification of the Predicate Device:

Predicate Device Name:	Neo Titanium mesh, CTi-mem
Applicant:	Neobiotech Co., Ltd.
Classification Product Code:	JEY
Regulation number:	872.4760
Device Class:	II
510(k) Number:	K111761

5.6 Identification of the Reference Device I:

Predicate Device Name:	SMARTbuilder System

Applicant:	OSSTEM Implant Co., Ltd.
Classification Product Code:	JEY
Subsequent Product Code:	NHA
Regulation number:	872.4760
Device Class:	II
510(k) Number:	K120951

5.7 Identification of the Reference Device II:

Predicate Device Name:	MC BIO "SuperTack" tack 3mm, 4mm and 5mm
Applicant:	Eli-Ka Technologies
Classification Product Code:	DZL
Regulation number:	872.4880
Device Class:	II
510(k) Number:	K151540

5.8 Identification of the Reference Device III:

Predicate Device Name:	GBR System
Applicant:	SURGIDENT Co., Ltd.
Classification Product Code:	JEY
Subsequent Product Code:	DZL
Regulation number:	872.4760
Device Class:	II
510(k) Number:	K170697

5.9 Indications for Use of the Device

"BoniPlus" Dental G-Mesh System is the non-absorbable membrane that is made of titanium metal to stabilize and support bone grafts in dento-alveolar bony defect sites.

5.10 Device Description

The "BoniPlus" Dental G-Mesh System is a non-absorbable titanium screen made of pure Titanium (ASTM F-67), that helps in bone neoformation. They come in many different lengths, widths and thicknesses.

The class II components under 21 CFR 872.4760 (JEY product code) are as below:

Name	Material	Model quantity	Dimension
Dental G-Mesh	TiGr2	11	Thickness: 0.1, 0.3 mm L1: 9.0, 25, 40, 50, 60 mm L2: 9.5, 17, 20, 30, 50, 60 mm
Mesh Screw	Ti-6Al-4V	2	OD: 1.6 mm Hex: 2.5 mm L: 8, 12 mm
Screw Cap		1	Hex: 1.27 mm Height: 3.0 mm
Tack	Ti-6Al-4V	1	Height: 2.5 mm

5.11 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, "BoniPlus" Dental G-Mesh System.

- Sterilization verification - gamma,
  according to ISO 11137-1, ISO 11137-2, ISO 11737-1, and ISO 11737-2.
- Shelf life - tensile test, dye penetration test, burst test, and creep test,
  according to ASTM F1980, ASTM F1929, ASTM F88/F88M, ASTM F1980, ASTM D882, BS EN 868-5, and ASTM F1140/F1140M
- Biocompatibility - *in vitro* cytotoxicity, sensitization, intracutaneous reactivity, and pyrogenicity,
  according to ISO 10993-1, ANSI/AAMI/ISO 10993-5, ISO 10993-10, ISO 10993-2, ANSI/AAMI/ISO 10993-12, USP <85>, and USP <161>.
  - For the pyrogenicity, we conducted endotoxin test (LAL test) to address

the presence of bacterial endotoxins. The result of endotoxin level for G-Mesh is <0.002 EU/device, for Mesh Screw & Screw Cap is <0.007 EU/device, and for Tack is <0.001 EU/device, which all meet the pyrogen limit specification we set of 0.01 EU/device.

- Bench performance - three-point bending test, axial pullout strength test, and torque test for insertion and removal,
  according to ASTM F382, ISO 14704, and ASTM F543.

All the test results demonstrate "BoniPlus" Dental G-Mesh System meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate and reference devices.

5.12 Clinical and Usability Testing

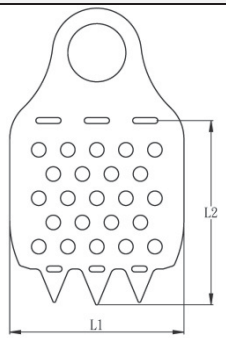
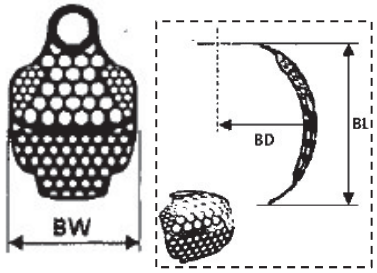
No clinical test data was used to support the decision of substantial equivalence.

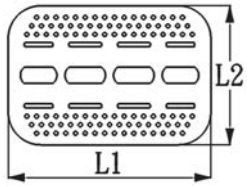
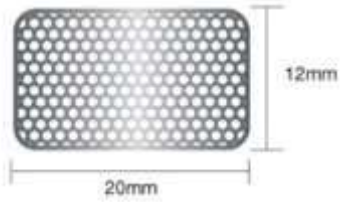
5.13 Substantial Equivalence Determination

The "BoniPlus" Dental G-Mesh System submitted in this 510(k) file is substantially equivalent in intended use, principle of operation/mechanism of action, safety and performance to the cleared device, Neo Titanium mesh, CTi-mem (K111761), SMARTbuilder System (K120951), MC BIO "SuperTack" tack 3mm, 4mm and 5mm (K151540), and GBR System (K170697). Differences between the devices are cited as below.

Item	Subject device	Predicate device	Reference device I	Reference device II	Reference device III	Substantial equivalence determination
Trade Name	"BoniPlus" Dental G-Mesh System	Neo Titanium mesh, CTi-mem	SMARTbuilder System	MC BIO "SuperTack" tack 3mm, 4mm and 5mm	GBR System	
510(k) No.	(to be assigned)	K111761	K120951	K151540	K170697	
Intended Use	"BoniPlus" Dental G-Mesh System is the non-absorbable membrane that is made of titanium metal to stabilize and support bone grafts in dento-alveolar bony defect sites.	For Stabilization and support bone grafts in dento-alveolar bony defect sites.	The SMARTbuilder is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.	The MC Bio Supertack tacks are used for the stabilization of absorbable and non-absorbable membranes during the bone tissue regeneration and bone repair in the maxillofacial or mandibular area. The MC Bio Supertack system is designed to stabilize barrier membranes onto cortical plate bone, this may be	The device is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity. Single patient use only.	***Equivalent*** All the subject, predicate, and reference devices are to stabilize and support of bone graft in dento-alveolar bony defect sites. The only difference with K170697 does not raise any new issue of substantial equivalence.

				used in maxillofacial or mandibular bone. General patient health, bone type and quality, and functional loads exerted should be considered and carefully evaluated prior to use.		
Components	Dental G-Mesh, Mesh Screw & Screw Cap, Tack Set	Mesh (Membrane), Mesh Spacer, Spacer Cap, Mesh Screw, Screw Cap	Membrane, Healing Abutment, Height (Spacer), Cover Cap	Tacks and associated instrumentation	Mesh and Screw	***Equivalent*** All the subject, predicate, and reference devices have mesh and its accessories to use in a system device. This difference does not raise any new issue of substantial equivalence.

Item	Subject device - G-Mesh	Reference device I - K120951	Substantial equivalence determination
Design			***Equivalent*** The substantive effect of the three claws on the bottom of subject device and relative position of the reference device is the same. It's used to fix the bone graft and avoid the gums growing too fast. This difference does not raise any new issue of substantial equivalence.
Material	TiGr2 from pure grade 2 Titanium (ASTM F-67)	TiGr2 from pure Titanium grade 2 (ASTM F-67)	***Same***
Dimensions (mm)	Thickness (Tk): 0.1 L1: 9.0 L2: 9.5	Thickness (Tk): 0.1 BW (Buccal width): 8.0, 10.0 BD (Buccal Distance): 5.5 BL (Buccal Length): 7, 9	***Equivalent*** The intended use of subject and reference devices is the same, and the result of comparative performance test of both devices is similar and meets the pre-defined criteria. This difference does not raise any new issue of substantial equivalence.
Sterilization	Sterile	Sterile	***Same***
Shelf life	3 years	5 years	***Equivalent*** The intended use of subject and reference devices is the same. This difference does not raise any new issue of substantial equivalence.

Item	**Subject device** - G-Mesh	**Predicate device** - K111761	**Substantial equivalence determination**
Design			***Equivalent*** The intended use of subject and predicate devices is the same. This difference does not raise any new issue of substantial equivalence.
Material	TiGr2 from pure grade 2 Titanium (ASTM F-67)	TiGr2 from pure Titanium grade 2 (ASTM F-67)	***Same***
Dimensions (mm)	Thickness (Tk): 0.1, 0.3 L1: 25, 40, 50, 60 L2: 17, 20, 30, 50, 60	Thickness (Tk): 0.07 L1: 20, 25,35,50 L2: 12, 20, 25, 35	***Equivalent*** The intended use of subject and predicate devices is the same, and the result of comparative performance test of both devices is similar and meets the pre-defined criteria. This difference does not raise any new issue of substantial equivalence.
Sterilization	Sterile	Sterile	***Same***
Shelf life	3 years	5 years	***Equivalent*** The intended use of subject and predicate devices is the same. This difference does not raise any new issue of substantial equivalence.

Item	**Subject device** - Mesh Screw & Screw Cap		**Reference device III** - K170697	**Predicate device** - K111761		**Substantial equivalence determination**
Design						***Equivalent*** The intended use, surgical procedure, treatment effect, and fixed way of subject and predicate devices are all the same. This difference does not raise any new issue of substantial equivalence.
Material	Ti-6Al-4V		Ti-6Al-4V			***Same***
Dimensions (mm)	OD: 1.6 Hex: 2.5 L: 8.0, 12.0	Hex: 1.27 L (Height): 3.0	Diameter: 0.85, 1.4, 1.6, 2.0 Length: 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 12.0	L: 7, 10, 13, 15	Hex: 4 Height: 3	***Equivalent*** The intended use of subject and predicate devices is the same, and the dimension of subject and reference devices is similar. This difference does not raise any new issue of substantial equivalence.
Sterilization	Sterile		Sterile			***Same***
Shelf life	3 years		5 years			***Equivalent*** The intended use of subject and predicate devices is the same. This difference does not raise any new issue of substantial equivalence.

Item	**Subject device** - Tack	**Reference device II** - K151540	**Substantial equivalence determination**
Design			***Equivalent*** The intended use of subject and reference devices is the same. This difference does not raise any new issue of substantial equivalence.
Material	Ti-6Al-4V	Ti-6Al-4V	***Same***
Height (mm)	2.5	3, 4, 5	***Equivalent*** The intended use of subject and reference devices is the same. This difference does not raise any new issue of substantial equivalence.
Sterilization	Sterile	Provided non-sterile End user sterilized	***Equivalent*** The subject device passed sterilization validation. This difference does not raise any new issue of substantial equivalence.
Shelf life	3 years	-	***Equivalent*** The subject device passed shelf-life validation. This difference does not raise any new issue of substantial equivalence.

5.14 Similarity and Difference

The "BoniPlus" Dental G-Mesh System has been compared with predicate device *Neo Titanium mesh, CTi-mem*, and reference devices *SMARTbuilder System* & *MC BIO "SuperTack" tack 3mm, 4mm and 5mm* & *GBR System*. The subject device has same intended use, principle of operation/mechanism of action, and similar technological specification as the predicate and reference devices. Although there are some specifications that are different between them, the performance test has been completed to demonstrate that the differences between these parameters would not impact the safety and effectiveness of the subject device. The subject device has also undergone safety and performance tests, and the results complied with the test requests. Therefore, the differences between the subject device and the predicate with reference devices do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate and reference devices in intended use, design and performance claims.

5.15 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the "BoniPlus" Dental G-Mesh System is substantially equivalent to the predicate and reference devices.