October 5, 2020

Neoss Limited
c/o Cherita James
Regulatory Consultant
M Squared Associates, Inc.
127 West 30th St. Floor 9
New York, New York 10001

Re: K201561
Trade/Device Name: Membrane Screws and Membrane Tacks
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: September 23, 2020
Received: September 25, 2020

Dear Cherita James:

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 Part 803) for devices or post-marketing 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.

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)*
K201561

Device Name
Membrane Tacks and Membrane Screws

Indications for Use *(Describe)*
Membrane Tacks and Membrane Screws are intended for fastening membranes during bone regenerative treatment. These membrane fastening means are in direct body contact, intended for temporary use only. Membrane fastening means are submerged and clinically implanted more than 30 days with an expected duration of implantation of three to nine months or until bone regeneration is complete taking into account which membrane and bone grafting materials are being used.

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."

K201561

510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for the Membrane Tacks and Membrane Screws 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: Neoss Ltd
Windsor House
Cornwall Road
Harrogate, HG1 2PW, UK
Establishment Registration Number: 3005846524

Contact: Cherita James
M Squared Associates, Inc.
127 West 30th St
9th Floor
New York, New York 10001
Ph: 347-954-0624
Fax: 702-562-9797
E-mail: CJames@MSquaredAssociates.com

Date of Submission: October 2, 2020

Proprietary Name: Membrane Tacks and Membrane Screws

Common Name: Intraosseous Tacks, Screws

Regulatory Class: II

Regulation: 872.4880

Product Code: DZL

Predicate Device(s): Meisinger Tacs, Hager and Meisinger GmbH K130682
Pro-fix Membrane Fixation Screws, Osteogenics K093719

Device Description: Membrane Tacks and Membrane Screws are regenerative membrane fastening devices available in 3mm length. The Membrane Tack is used in conjunction with a Tack Positioning Instrument, while the Membrane Screw is applied with the Neoss Implant Inserter. Regenerative membranes are designed to prevent ingrowth of gingival soft tissue into bony defects, in order to facilitate the bone formation during the repair process of the defect. Membrane Tacks and Screws are made of titanium while related instruments are made in stainless steel. The Membrane fastening devices are single-use only while the instruments are for multiple use.

Indications for Use: Membrane Tacks and Membrane Screws are intended for fastening membranes during bone regenerative treatment. These membrane fastening means are in direct body contact, intended for temporary use only. Membrane fastening means are submerged and clinically implanted more than 30 days with an expected duration of implantation of three to nine months or until bone regeneration is complete taking into account which membrane and bone grafting materials are being used.

Comparison to predicate device.

The claim of substantial equivalence of the Membrane Tacks and Membrane Screws to the products identified above is based on the comparison of the intended use, product technical characteristics, performance characteristics and product handling.

	Neoss	**Hager and Meisinger GmbH**	**Substantial Equivalence**
	Membrane Tack	Meisinger Tac (only)	
510(k) No.	K201561	K130682	
			Device designs are similar and suitable for their intended use.
Product Code	DZL Intraosseous fixation screw	DZL Intraosseous fixation screw	Substantially equivalent
Intended Use	Membrane Tacks are intended for fastening membranes during bone regenerative treatment. These membrane fastening means are in direct body contact, intended for temporary use only. Membrane fastening means are submerged and clinically implanted more than 30 days with an expected duration of implantation of three to nine months or until bone regeneration is complete taking into account which membrane and bone grafting materials are being used.	Meisinger Tacs are used for the fixation of membranes (resorbable membranes nonresorbable membranes) to the bone structure. Tacs are intended for single use only.	Substantially equivalent. Both devices have the same intended use (membrane fastening) for the same anatomical site (oral cavity) during bone regeneration. Though not specified by Neoss, the membrane tacks are intended for use with both resorbable membranes nonresorbable membranes. Meisinger has not specified the duration and implantation details however this

	Neoss	Hager and Meisinger GmbH	Substantial Equivalence
			can be assumed by the intention of the application of a dental membrane. The differences in the indication statements do not represent a difference in the intended use clinically and do not affect the safety and effectiveness of the subject device.
Material Composition	Titanium alloy grade 5 (ASTM F136)	Titanium alloy grade 5 (ASTM F136)	Substantially equivalent
Dimensions	Head diameter 2.5mm, Length 3.0mm	Head diameter 2.5mm, Length 3.5mm	The Neoss device is within the range of dimensions of the predicate and other commercially available tacks
Handling and placement	Pick up the Tack by firmly pushing the Tack Positioning Instrument, Insert thru membrane and gently tap Tack with mallet	Pick up the Tack by firmly pushing the Tack Positioning Instrument, Insert thru membrane and gently tap with mallet	
Removal	pry the head of the Tack from the underlying membrane using a thin and flat tool, such as a scalpel blade.	Unknown for Tacs	The Neoss Membrane Tack is removed by similar methods to currently marketed dental membrane tacks.
Bone stability	Barbed tip	Barbed tip	Substantially equivalent
Duration of use	implanted more than 30 days with an expected duration of implantation of three to nine months or until bone regeneration is complete taking into account which membrane and bone grafting materials are being used.	unknown	The duration of use for the Neoss products is the same as other commercially available tacks, they are intended to be removed at the time healing is achieved
Sterility	sterile	delivered non-sterile/ autoclavable	Packaging, sterilization and transport have been validated.
Reprocessing	No – single use	No – single use	Substantially equivalent
Biocompatible	Yes, materials and manufacturing process	Yes, materials	Neoss Tacks manufacturing processes and

	Neoss	Hager and Meisinger GmbH	Substantial Equivalence
			materials are evaluated for biocompatibility for their intended use. Meisinger processing is unknown, but material is the same.

	Neoss	Osteogenics	Substantial Equivalence
	Membrane Screw	Pro-Fix Screw (only)	
510(k) No.	K201561	K093719	
Product Code	DZL Intraosseous fixation screw	DZL Intraosseous fixation screw	Substantially equivalent
			Device designs are similar and suited for intended use.
Intended Use	Membrane Screws are intended for fastening membranes during bone regenerative treatment. These membrane fastening means are in direct body contact, intended for temporary use only. Membrane fastening means are submerged and clinically implanted more than 30 days with an expected duration of implantation of three to nine months or until bone regeneration is complete taking into account which membrane and bone grafting materials are being used.	The Pro-FixTM Precision Fixation System is used to stabilize, fixate and/or support bone grafts, bone filling materials and/or barrier membranes used for regeneration of bone in the oral cavity.	Same intended use for fixation of membranes only. Osteogenics has not specified the duration and implantation details however this can be assumed by the intention of the application of a dental membrane. The differences in the indication statements do not represent a difference in the intended use clinically and do not affect the safety and effectiveness of the subject device.
Material Composition	Titanium alloy grade 5 (ASTM F136)	Titanium alloy grade 5 (ASTM F136)	Same material
Dimensions	Diameter Head 2.6mm, Thread 1.5mm & length 3.2mm	Diameter: Thread 1.5mm, length 3.mm	Comparable screw dimensions and performance testing confirms adequate for intended use.

	Neoss	**Osteogenics**	**Substantial Equivalence**
Handling and placement	Pick up the Screw by firmly pushing the tip of a Neoss Implant Inserter into the head of the Screw, Insert the Screw through the membrane into the bone applying a torque of less than 10 Ncm.	Cruciform driver	Neoss has confirmed instrument performs as intended for placement.
Removal	unscrew the Membrane Screws using the tip of a Neoss Implant Inserter	Unknown	Neoss has confirmed instrument performs as intended for removal
Duration of use	implanted more than 30 days with an expected duration of implantation of three to nine months or until bone regeneration is complete taking into account which membrane and bone grafting materials are being used.	implanted more than 30 days with an expected duration of implantation of three to nine months or until bone regeneration is complete taking into account which membrane and bone grafting materials are being used	Substantially equivalent duration of use
Sterility	sterile	sterile	Substantially equivalent
Reprocessing	No-single use	No-single use	Substantially equivalent
Biocompatible	Yes, material and manufacturing processes	Yes, materials	Neoss Tacks manufacturing processes and materials are evaluated for biocompatibility for their intended use. Osteogenics processing is unknown, but material is the same.

Technological Characteristics

The Membrane Screws and Membrane Tacks are substantially equivalent to the predicates identified above with regard to materials, dimensions, product packaging and handling, and placement and removal methods.

Both Membrane Tacks and Screws, like the predicate devices, are provided in a sterile form.

Performance Testing

Membrane Screws and Membrane Tacks are in conformity with the following standards.

Standard	Recognition Number
EN ISO 11137-1:2015 Sterilization of health care products — Radiation — Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices	14-428
EN ISO 11137-2:2015 Sterilization of health care products — Radiation — Part 2 Establishing the sterilization dose	14-409
ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.	2-258

Sterilization: A dose of 25 kGy is chosen as sterilization dose by gamma irradiation. Method VDmax25 according to standard EN ISO 11137-2 is applied for all Neoss products that are terminally sterilized (SAL 10^{-6}). The Membrane Tacks and Screws are manufactured of the same material (Titanium alloy grade 5) and packaged identically to various 510k cleared Neoss Implant System (implants/abutments/screws K083561, K090452, K113376), which would be considered “worst case” for sterilization when compared to the Membrane Tacks and Screws.

Shelf life: Membrane Tacks and Screws are provided sterile for single patient use. They are delivered packaged in a PET blister with peel-open paper lid housed in a protective rigid plastic case. The packaging utilized is a standard packaging for terminally sterilized Neoss Implant Systems. The products sterilized with gamma irradiation and packaged as described above have been verified to support 5 years shelf life (Ageing Validation including accelerated ageing, real time ageing and peel force testing have been performed and are documented to support 5 year shelf life claim).

Biocompatibility: Membrane Tacks and Membrane Screws are characterized as permanent implants (up to 1 year), contacting tissue and bone. No new biocompatibility testing has been performed, as the subject devices are substantially equivalent to Neoss Access Abutment (K081851) and Crystaloc Abutment Screw (K150669) with regards to materials and processing. The Neoss patient contacting instruments

(implant inserter and tack positioning instrument) only have very brief / transitory contact with the body. No coating or lubricants are left in contact with body tissues after the devices are removed. Per ISO 10993-1:2018 section 5.3.2 such devices do not require biocompatibility testing.

Instrument cleaning and sterilization: Membrane Tack and Screw Cassette, Tack Positioning Instrument and Neoss Implant Inserter cleaning and sterilization recommendations were validated on more complex, multicomponent Neoss instruments of the same materials. Cleaning validations included soiling, mechanical cleaning, and residual testing for hemoglobin and protein. Sterilization parameters were evaluated to a SAL 10^{-6} using the biological indicator overkill method. Test articles were inoculated as outlined in AAMI TIR12 and sterilized using the validated full cycle sterilization parameters and dry time. Validation results confirmed the SAL was achieved with recommended parameters and no evidence of moisture.

Performance evaluations of the Membrane Tacks was conducted to evaluate the insertion and removal forces and found them to be comparable to the predicate device and acceptable for their intended use. Performance evaluations of the Membrane Screws was conducted to evaluate the insertion torque of the device and found them comparable to the values of the predicate device.

Clinical Data: Clinical data is not required to establish substantial equivalence in this submission.

Conclusion

Membrane Tacks and Membrane Screws substantially equivalent, to the
Meisinger Tacs (K130682) and the Osteogenics Pro-fix Membrane Fixation Screws (K093719). They share similar indications for use, technological and performance characteristics.