February 13, 2024

Sofradim Production
Mickaël Nicolas
Principal Regulatory Affairs Specialist
116, Avenue du Formans
Trévoux, 01600, France

Re: K233661
Trade/Device Name: Transorb™ Self-Gripping Resorbable Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWT, OOD, FTL
Dated: November 14, 2023
Received: November 15, 2023

Dear Mickael Nicolas:

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.

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.02.13 07:48:57 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
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and Infection Control Devices
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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)*
K233661

Device Name
Transorb™ Self-Gripping Resorbable Mesh

Indications for Use *(Describe)*
Transorb™ Self-Gripping Resorbable Mesh is intended to be used for the reinforcement of abdominal wall soft tissues where weakness exists in open procedures involving ventral hernia repair.

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

510(k) Number	**K233661**
Date Prepared:	January 11, 2024
Submitter:	Sofradim Production (subsidiary of Covidien llc) 116, avenue du Formans 01600 Trevoux, France Telephone: +33 (0)4 74 08 90 00 Fax: +33 (0) 4 74 08 90 02
Contact:	Mickaël Nicolas Regulatory Affairs Principal Specialist 116, avenue du Formans 01600 Trevoux, France Phone: +33 (0)4 74 08 90 00 Email: mickael.nicolas@medtronic.com
Name of device:	
Trade/Proprietary name:	Transorb™ Self-Gripping Resorbable Mesh
Common name:	Surgical Mesh
Classification name:	General And Plastic Surgery Panel number Product code: OWT, FTL, OOD Regulation number: 21 CFR 878.3300
Predicate Device:	
Trade/Proprietary name:	TIGR® Matrix Surgical Mesh
Common name:	Surgical Mesh
Classification name:	General And Plastic Surgery Panel number and product code: OWT, FTL, OOD Regulation number: 21 CFR 878.3300
510(k) Number:	K191749
Manufacturer:	Novus Scientific AB, Virdings Alle 2, Uppsala, SE Se-754 50
Reference Device 1:	
Trade/Proprietary name:	ProGrip™ Self-Gripping Polyester Mesh
Common name:	Surgical Mesh
Classification name:	General And Plastic Surgery Panel number and product code: FTL Regulation number: 21 CFR 878.3300
510(k) Number:	K220586
Manufacturer:	Sofradim Production (subsidiary of Covidien llc) 116, avenue du Formans 01600 Trevoux, France

Reference Device 2:

Trade/Proprietary name:	Phasix™ Mesh
Common name:	Surgical Mesh
Classification name:	General And Plastic Surgery Panel number and product code: OOD Regulation number: 21 CFR 878.3300
510(k) Number:	K161424
Manufacturer:	Davol Inc. 100 Crossings Boulevard Warwick, RI 02886

Device Description:

Transorb™ Self-Gripping Resorbable Mesh is designed for ventral hernia repair when placed in an extraperitoneal space by open surgical approach.

Transorb™ Self-Gripping Resorbable Mesh is made of a fully resorbable bi-dimensional Poly-L-lactide, poly-trimethylene carbonate copolymer (PLLA/TMC) monofilament textile with monofilament PLLA/TMC absorbable grips on one side.

Transorb™ Self-Gripping Resorbable Mesh is available in different shapes and sizes.
Mesh composition:

Product codes	Shape	Dimensions (length x width)
TSB1510	Rectangular	10cm x 15cm
TSB2020	Square	20cm x 20cm
TSB3030	Square	30cm x 30cm
TSB4030	Rectangular	30cm x 40cm

Poly-L-lactide, poly-trimethylene carbonate copolymer (PLLA/TMC) monofilament yarn (up to 21g).

The detailed composition refers to the estimated maximum amount of each material and substance to which a patient can be exposed when 1 unit of the largest size of Transorb™ Self-Gripping Resorbable Mesh is implanted (i.e 40 x 30 cm). These amounts will be less for smaller sizes or if the mesh is trimmed by the practitioner prior to implantation.

Transorb™ Self-Gripping Resorbable Mesh is a macro-porous mesh knitted from resorbable monofilament PLLA/TMC yarns. It has been designed to reinforce soft tissues where weakness exists by providing strength and tissue integration throughout the expected healing period. Transorb™ Self-Gripping Resorbable Mesh has absorbable PLLA/TMC grips on one side that facilitate positioning and contribute to fixation. The PLLA/TMC mesh and grips degrade and resorb in vivo by hydrolysis in 36 to 60 months and are metabolized by the body into CO_2 and H_2O.

The macro-porous textile provides strength required to withstand biomechanical stresses throughout the healing period, while allowing

for tissue ingrowth. As the textile integrates, host tissue ingrowth is intended to provide strength to the repair.
Preclinical studies showed that the mesh maintains mechanical characteristics to reinforce the abdominal wall in vivo for at least 20 weeks and progressively resorbs.
Preclinical studies showed that the grips contribute to the fixation of the mesh to surrounding tissue in vivo for at least 4 weeks.

At 18 to 24 months, mesh degradation is nearly complete. The remaining mesh fibers are essentially resorbed in 36 to 60 months post-implantation. The total resorption period depends on numerous factors including unique patient physiology.

Intended Use:

Transorb™ Self-Gripping Resorbable Mesh is intended to be used for the reinforcement of abdominal wall soft tissues where weakness exists.

Indications for use:

Transorb™ Self-Gripping Resorbable Mesh is intended to be used for the reinforcement of abdominal wall soft tissues where weakness exists in open procedures involving ventral hernia repair.

Summary comparing the technological characteristics of the subject, predicate device and reference devices:

The subject device Transorb™ Self-Gripping Resorbable Mesh is substantially equivalent to the predicate device TIGR® Matrix Surgical Mesh (K191749) in terms of indications.

	Transorb™ Self-Gripping Resorbable Mesh (K233661)	**TIGR® (K191749) Predicate device**	**Comparison**
Intended Use	Reinforcement of abdominal wall soft tissue where weakness exists.	Reinforcement of soft tissue where weakness exists.	**Similar**
Indications for use	Transorb™ self-gripping resorbable mesh is intended to be used for the reinforcement of abdominal wall soft tissues where weakness exists in open procedures involving ventral hernia repair.	Procedures involving soft tissue repair, such as for the repair of hernias or other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result	**Similar**
Method of Insertion	Open	Open and laparoscopic	**Similar**
Location of Mesh placement	Extraperitoneal	Extraperitoneal	**Same**
Defect Closure	Recommended	Recommended	**Same**
Classification	OWT, OOD, FTL per 21 CFR 878.3300	OWT, OOD, FTL per 21 CFR 878.3300	**Same**

Materials	Fully resorbable textile (polymeric) made of copolymer of polylactide acid and trimethylene carbonate yarns (PLLA/TMC)	Fully resorbable textile (polymeric) made of (i) copolymer of glycolide, lactide and trimethylene carbonate (PGA/PLA/TMC) and (ii) copolymer of lactide and trimethylene carbonate (PLLA/TMC)	**Similar**
Shape	Flat Sheet Square, rectangular, with round corners	Flat Sheet Rectangular	**Similar**
Sizes	10x15cm, 20x20cm, 30x30cm and 30x40cm The mesh may be recut as needed	10x15cm, 15x20cm and 20x30cm The mesh may be recut as needed	**Different**
Texture	Two-dimensional monofilament textile with monofilament absorbable grips on one side of the mesh Porosity: pore size of 1.4mm x 1.4mm at the time of implantation	Two-dimensional multifilament textile Porosity: pore size of 1.0 mm x 1.0 mm at the time of implantation	**Different**
Sterilization	Ethylene Oxide	Ethylene Oxide	**Same**

Both predicate and subject devices are resorbable flat sheet meshes. Differences in terms of material, sizes, and texture (pore size and presence of grips) have been evaluated and do not raise new questions of safety or effectiveness. Performance testing has demonstrated substantial equivalence for biocompatibility, mechanical properties such as strength, human factors evaluation, sterilization, packaging, and transport.

The device ProGrip™ Self-Gripping Polyester Mesh previously cleared under K220586 is introduced as a reference device for its gripping design feature to support the design of the subject device. Both reference and subject devices have resorbable grips on one side and are equivalent in terms of intended use.

The device Phasix™ Mesh previously cleared under K161424 is introduced as a reference device because it includes large sizes (up to 50*50cm) and it is a fully resorbable mesh. Both reference and subject devices are resorbable meshes with large mesh sizes.

Materials: Transorb™ Self-Gripping Resorbable Mesh has been evaluated and found compliant with ISO Standard 10993-1.

Performance data: The performance of Transorb™ Self-Gripping Resorbable Mesh has been evaluated through bench tests, *in vitro* and *in vivo* studies. These studies demonstrate that the subject device and predicate device TIGR® Matrix Surgical Mesh (K191749) have substantially equivalent performance characteristics. The following performance data is provided:

a. Biocompatibility Testing

Biocompatibility testing and classification has been selected and performed in accordance with ISO 10993, Biological evaluation of Medical Devices, Part 1: Evaluation and testing within a risk management process. Transorb™ Self-Gripping Resorbable Mesh is classified as an implant with permanent contact.
A complete chemical characterization was performed in accordance with ISO 10993-18. No risk of chronic toxicity, carcinogenicity or reproductive and developmental toxicity has been identified so nor through literature review and material characterization, nor in Toxicological Risk Assessment performed on finished product extractables profile. Available biological safety data on the Transorb™ Self-Gripping Resorbable Mesh are listed hereafter. Testing was performed on sterilized finished devices.

Studies	Standards	Conclusion
Cytotoxicity	ISO10993-5	Pass
Sensitization	ISO 10993-10	Pass
Intracutaneous irritation	ISO10993-10	Pass
Acute systemic toxicity	ISO10993-11	Pass
Material mediated pyrogenicity	ISO10993-11	Pass
Hemolysis	ISO 10993-4	Pass
Genotoxicity: bacterial reverse mutation -Ames	ISO10993-3	Pass
Genotoxicity: mouse lymphoma	ISO10993-3	Pass
Subacute systemic toxicity	ISO 10993-11	Pass
Subchronic systemic toxicity	ISO 10993-11	Pass
Local tissue effects (28D – 10W -26W - 52W – 78W)	ISO 10993-6	Pass
In vivo degradation	ISO 10993-9	Pass

Applicable ISO 10993-1 Biocompatibility evaluation was conducted and demonstrates that the subject device is biocompatible for its intended body contact and duration.

b. Bench Testing

Bench tests have been performed in accordance with the FDA Guidance *"Guidance for the Preparation of a Premarket Notification Application of a Surgical Mesh"* issued March 2, 1999 to evaluate the performance characteristics of the subject device Transorb™ Self-Gripping

Resorbable Mesh in comparison with the predicate TIGR Matrix Surgical Mesh (K191749). The following finished product physical and mechanical performances were assessed:

Test method	Applicable standard / Test method	Conclusion
Pore size	Internal test method. Mesh pore size is measured on a profile projector. Biggest pores extreme height and width are measured, the sample being free of any stresses.	Regarding physical aspect, the proposed device (Transorb™ Self-Gripping Resorbable Mesh) is substantially equivalent to TIGR® Matrix Surgical Mesh (K191749).
Surface density	ISO 3801: 1977	
Thickness	ISO 9073-2: 1997	
Bursting strength and deflection	ASTM 06797-15	Regarding mechanical aspect in case of 510(k) registration, the proposed device (Transorb™ Self-Gripping Resorbable Mesh) is substantially equivalent to TIGR® Matrix Surgical Mesh (K191749).
Breaking strength and elongation at break	ISO 13934-1: 2013	
Tear strength	ISO 4674:1977 - method A2	
Suture pull-out strength	Internal test method. Suture pull-out strength is measured on a traction testing machine using dedicated specimens and test conditions	

c. Animal Testing

Porcine study - Reinforcement performance

In vivo pre-clinical tests on large animal model were conducted in comparison with the predicate TIGR Matrix Surgical Mesh (K191749) to evaluate Transorb™ Self-Gripping Resorbable Mesh reinforcement performance during healing period (up to 20 weeks following implantation):

- Mechanical performance (breaking strength – ball burst) of the repaired abdominal wall defects sites using a ball burst testing method.
- Quality of tissue repair and of mesh tissue integration was also assessed by histologic examination.

Rabbit study – Degradation/Integration

In vivo testing has been performed in comparison with predicate TIGR Matrix Surgical Mesh (K191749) to evaluate:

- Local tissue effects per requirements of ISO 10993-6 (2016) and FDA Guidance Use on International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"
- Tissue integration and tissue ingrowth;
- Degradation profile

Porcine study – Gripping performance

In vivo testing has been performed in comparison with predicate TIGR Matrix Surgical Mesh (K191749) to evaluate:

- Contribution of the grips to the fixation of the mesh to the surrounding tissue in early stages after implantation
- Quality of tissue repair and mesh tissue integration by histologic examination.

These tests demonstrate the safety and performance of the subject device for its intended use and substantial equivalence to the primary predicate device.

d. Human Factors Testing

Usability tests were conducted in accordance with IEC 62366-1 and demonstrate that the subject device Transorb™ Self-Gripping Resorbable Mesh is substantial equivalent for the intended users, uses and use environments.

e. Shelf-life

The shelf-life of the subject Transorb™ Self-Gripping Resorbable Mesh was demonstrated by the results of the real time studies performed on Transorb™ Self-Gripping Resorbable Mesh (representative of final sterile product), that includes testing of the product mechanical performances and the ability of packaging to maintain sterile barrier. Based on these results, a shelf life of 36 months was assigned for the subject Transorb™ Self-Gripping Resorbable Mesh.

f. Clinical data

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion:
All testing demonstrates that the subject device Transorb™ Self-Gripping Resorbable Mesh is substantially equivalent to the predicate device, TIGR Matrix Surgical Mesh (K191749).