March 26, 2020

Novus Scientific AB
℅ Loredana Guseila
Director of Regulatory and Clinical Affairs
Cygnus Regulatory, LLC
5555 E Palo Verde Drive
Paradise Valley, Arizona 85253

Re: K191749
Trade/Device Name: TIGR Matrix Surgical Mesh, TIGR Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWT, OOD, FTL
Dated: February 17, 2020
Received: February 25, 2020

Dear Loredana Guseila:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K191749

Device Name
TIGR Matrix Surgical Mesh

Indications for Use *(Describe)*
The TIGR Matrix Surgical Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in 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.

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

I. SUBMITTER

Novus Scientific, AB Address
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SE-754 50 Uppsala, Sweden

Contact Person: Thomas Engström
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Facsimile: +46 (0)18 700 11 51

II. DEVICE

510(k) Number: K191749
Trade Name of the Device: TIGR® Matrix Surgical Mesh
Common or Usual Name: Mesh, Surgical, Absorbable, Abdominal Hernia
Classification Name: General & Plastic Surgery
Product Codes: OWT, OOD, FTL
Regulation: 21 CFR, 878.3300

III. PREDICATE DEVICE

Primary Predicate: CR. Bard, Inc. Phasix Mesh (K161424)
Refence Predicate: Novus Scientific, AB TIGR® Matrix Surgical Mesh (K163005)

IV. DEVICE DESCRIPTION

Technological Characteristics:

The technological characteristics of the device are the same as submitted in the reference predicate (K163005) and very similar to the primary predicate (K161424).

TIGR™ Matrix Surgical Mesh is knitted from two different synthetic resorbable fibers, possessing different degradation characteristics. The fast-resorbing fiber, making up approximately 40% of the matrix by weight, is a copolymer of glycolide, lactide, and trimethylene carbonate. The slow-resorbing fiber, making up approximately 60% of the matrix by weight, is a copolymer of lactide, and trimethylene carbonate. Both fibers degrade by bulk hydrolysis once implanted, resulting in a decreasing strength retention followed by mass loss of the fibers. *In vitro* testing showed that the fast-resorbing fiber (glycolide, lactide and trimethylene carbonate) loses its mechanical strength after 2 weeks and *in vivo* studies in the abdominal wall of sheep showed that the fast-resorbing fiber is fully absorbed after 4 months. The same *in vitro* testing showed that the slow-resorbing fiber (lactide and trimethylene carbonate) maintains its mechanical strength for 6 months and in vivo studies in the abdominal wall of sheep indicated that the slow-resorbing fiber is absorbed after approximately 36 months.

Resorbable fibers

MG17 is composed of polyglycolide and trimethylene carbonate, in a 10-fiber yarn construction. SMC7 is a 43-fiber yarn construction of polylactide and trimethylene carbonate. The MG17 content of the mesh is 40%

Knitting pattern

The implant is knitted using warp-knitting, knitting with interlocking knits that prevent unraveling, to produce a diamond pattern where the MG17 fibers are traversing the open apertures and restricting the mobility of the implant during an initial time period.

Mechanical characteristics

The initial burst strength of the mesh implant is above 350N. This strength can be compared with existing commercially available products that range between 170-750N. The mechanical strength of the implant will decrease over time as a result of resorption of the fibers. Between 0 and 26 weeks the mechanical strength is kept well above 16N/cm which is above the highest force acting on the abdominal wall. Following 26 weeks the mechanical strength of the mesh implant is gradually lost due to degradation and the newly formed tissue is strong enough to carry the load applied to it. This is the same as for the reference predicate and similar to the primary predicate.

Principles of Operation

The TIGR® Matrix Surgical Mesh is an absorbable, polymeric, surgical mesh for soft tissue repair, including hernia repair. The principles of operation are the same as the reference and primary predicate devices. There is no change to the device from the reference predicate (K163005), including principle of operation, except for changes in the indication and labeling, and expansion of the shelf life dating from 36 months to 48 months based on successful completion of accelerated and real-time aging studies.

Substantial Equivalence

The TIGR Matrix Mesh is substantially equivalent to the primary predicate the C.R. Bard Phasix Mesh (K161424), including the proposed indication for use, contraindications, and applicable warnings. The subject device is the exact same device as the reference predicate, the TIGR Surgical Matrix Mesh (K163005), except for proposed labeling changes to match the primary predicate's labeling.

The subject device and the primary and reference predicates have the same general intended use and equivalent indications, contraindications, technological characteristics, and principles of operation. A substantial equivalence matrix comparing the similarities and differences between the subject device and its predicate devices is provided below.

V.INDICATIONS FOR USE

The TIGR® Matrix Surgical Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in 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.

The TIGR® Matrix Surgical Mesh is an Rx prescription device per 21 CFR Part 801, Subpart D.

VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	Subject Device TIGR® Matrix Surgical Mesh (K191749)	Primary Predicate Phasix™ Mesh (K161424)	Reference Predicate Device TIGR® Matrix Surgical Mesh (K163005)	Equivalency Discussion
Trade Name	**TIGR® Matrix Surgical Mesh**	**Phasix™ Mesh**	**TIGR® Matrix Surgical Mesh**	N/A
Classification	Surgical Mesh	Surgical Mesh	Surgical Mesh	Same
Product Code	OWT, OOD, FTL	OOD	OWT, FTL	Equivalent
Intended Use/Indication for Use	The TIGR® Matrix Surgical Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in 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.	The Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.	N/A	Equivalent to Primary Predicate.
Contraindications	TIGR® Matrix Surgical Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.	Because PHASIX™ Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.	N/A	Same as the Primary Predicate.
Warnings	The safety and effectiveness of TIGR® Matrix Surgical Mesh in bridging repairs has not been evaluated or established.	The safety and effectiveness of PHASIX™ Mesh in bridging repairs has not been evaluated or established.	N/A	Equivalent to Primary Predicate
Regulation	21 CFR 878.3300	21 CFR 878.3300	21 CFR 878.3300	Same
Regulatory Class	Class II	Class II	Class II	Same
Use	Single Use	Single Use	Single Use	Same
Target Population	Adult Population	Adult Population	Adult Population	Same
Where Used	Operating Room or MR Suite	Operating Room or MR Suite	Operating Room or MR Suite	Same
	MRI/Diagnostic / Surgical Room	MRI/Diagnostic / Surgical Room	MRI/Diagnostic / Surgical Room	Same
Energy Used	None	None	None	Same

Characteristic	Subject Device TIGR® Matrix Surgical Mesh (K191749)	Primary Predicate Phasix™ Mesh (K161424)	Reference Device TIGR® Matrix Surgical Mesh (K163005)	Equivalency Discussion
Human Factors	Labeling indicates size and length	Labeling indicates size and length	Labeling indicates size and length	Same
	Can be manipulated with gloved hand	Can be manipulated with gloved hand	Can be manipulated with gloved hand	Same
Design	Designed to be placed in the abdominal area	Designed to be placed in the abdominal area	Designed to be placed in the abdominal area	Same
	Absorbable	Absorbable	Absorbable	Same
	Use in reinforcement of soft tissue where weakness exists	Use in reinforcement of soft tissue where weakness exists	Use in reinforcement of soft tissue where weakness exists	Same
	Repair of hernias and other soft tissues	Repair of hernias and other soft tissues	Repair of soft tissues	Same as primary predicate
Performance	Clinical data for hernia repair	No Clinical Data	No Clinical Data	Equivalent to primary Predicate and the same as reference predicate.
Biocompatibility	Biocompatibility testing and classification has been selected and performed in accordance with ISO 10993, Biological evaluation of Medical Devices, Part 1: Evaluating and Testing.	Biocompatibility testing conducted to date per the requirements of ISO 10993-1 indicates the device is biocompatible for its intended use as a permanent, tissue-contacting, implant device.	Biocompatibility testing and classification has been selected and performed in accordance with ISO 10993, Biological evaluation of Medical Devices, Part 1: Evaluating and Testing.	Same
Sterilization	Sterile EO	Sterile EO	Sterile EO	Same
Packaging	Tyvek envelope and foil pouch	Tyvek envelope and foil pouch	Tyvek envelope and foil pouch	Same
Shelf Life	48 months	Unknown	36 months	Equivalent

Characteristic	Subject Device TIGR® Matrix Surgical Mesh (K191749)	Primary Predicate Phasix™ Mesh (K161424)	Reference Device TIGR® Matrix Surgical Mesh (K163005)	Equivalency Discussion
Mesh Thickness (mean)	0.687 mm	Unknown	0.687 mm	Same as reference predicate.
Area Weight/Density (mean)	$125 \leq X \leq 170$ g/m^2	Unknown	$125 \leq X \leq 170$ g/m^2	Same as reference predicate.
Porosity	$20 \leq X \leq 40$ %	Unknown	$20 \leq X \leq 40$ %	Same as reference predicate.
Weave Characteristics	Multifilament, warp, knitted, mesh	Knitted P4HB monofilament	Multifilament, warp, knitted, mesh	Equivalent
Ranges of sizes	100 X 150 to 200 X 300 mm	3” Circle 4” x 6” Rectangle 6” x 8” Rectangle 8” x 10” Rectangle 10” x 12” Rectangle 4.5” Circle 2.4” x 6.3” Rectangle 3" x 3" Square 3" x 6.3" Rectangle 3" x 8" Rectangle 4" x 4" Square 4" x 8" Rectangle 4" x 10" Rectangle 6" x 10" Rectangle 6" x 12" Rectangle 8" x 8" Square 8” x 12” Rectangle 8" x 16" Rectangle 10" x 16" Rectangle 12" x 12" Square 12" x 18" Rectangle 14" x 14" Square 16" x 16" Square 18" x 18" Square 19.5" x 19.5" Square	100 X 150 to 200 X 300 mm	Equivalent
Materials	Copolymers (Glycolide, L-lactide and Trimethylene carbonate)	Poly-4-Hydroxybutyrate	Copolymers (Glycolide, L-lactide and Trimethylene carbonate)	Equivalent
Sterility	SAL 10^{-6}	SAL 10^{-6}	SAL 10^{-6}	Same

VII. PREFORMANCE DATA

The subject device is the same as the reference predicate the TIGR® Matrix Surgical Mesh (K163005). All relevant preclinical test results/reports for the TIGR® Matrix Surgical Mesh were submitted in K163005. Additional performance data provided with this submission is to support an expansion of shelf life dating from 36 to 48 months.

a. Biocompatibility

The subject device is the same as the reference predicate the TIGR® Matrix Surgical Mesh (K163005). The devices are identical with the same materials of construction, processing, packaging, and sterilization. Applicable ISO 10993-1 Biocompatibility Testing was conducted and demonstrates that the subject device is biocompatible for its intended body contact and duration.

b. Bench Testing

Bench testing performed is described in (K163005) for the reference predicate, which is the same device as the subject device except for the proposed labeling changes. These tests demonstrate the safety and performance of the subject device for its intended use and substantial equivalence to the primary predicate device.

c. Animal Testing

Animal testing performed is described in (K163005) for the reference predicate, which is the same device as the subject device except for the proposed labeling changes. 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

Human factors testing performed is described in (K163005) for the reference predicate, which is the same device as the subject device except for the proposed labeling changes, which do not impact human factors performance. The TIGR surgical mesh has been used in US clinics since 2010. These tests demonstrate the safety and performance of the subject device for its intended use and substantial equivalence to the primary predicate device.

e. Clinical Data

Introduction: Clinical data were not required to demonstrate substantial equivalence of the TIRG Matrix Surgical Mesh to the predicate device. However, real-world clinical evidence were included with this submission to support the safety and performance of the TIGR Matrix Surgical Mesh for its proposed expanded indication for use to match the primary predicate device's labeling. Long-term follow-up was obtained.

Methods: The use of hernia mesh is a common practice in abdominal wall reconstruction (AWR) operations. A surgical hernia program implemented the principles of Clinical Quality Improvement (CQI), under the CQI regulations and applicable national and local laws, including the rules and regulations of the Privacy Rule 45 CFR Part 160 and Subparts A and E of Part 164 (the HIPAA Privacy Rule) and the US Government Agency for Healthcare Research and Quality (AHRQ). Patients were informed of the CQI process and allowed to choose whether to receive any particular treatment option.

Commercially available TIGR Surgical Matrix Mesh was implanted as part of the surgeons' clinical practice, along with the use of a variety of other hernia meshes (resorbable and permanent) used for abdominal wall reconstruction (AWR). Patients were offered the option of various surgical approaches and meshes (including the option of not receiving a mesh). Surgical options included open and laparoscopic approaches. Patients with active infection were not offered a laparoscopic approach**.**

Results: A total of 91 patients undergoing AWR were included between 8/2011 and 9/2015 (49 months). There were 58 female (64%) and 33 male (36%) patients. The average age was 57.2 years (28 – 80). The average BMI was 34.0 (17.6 – 53.4). There were 52 patients (57%) with recurrent hernias. Mean hernia defect size was 306.6 cm2 (24 – 720) and mean mesh size was 471.7 cm2 (112 – 600). Outcomes included a mean length of stay of 7.5 days (0 – 49), a recurrence rate of 12% (11/91) and a wound complication rate of 27% (25/91). The recurrence rate decreased to 4.5% (3/66) after several improvements, including adopting a transversus abdominus release (TAR) approach, were implemented. There were no mesh related complications and no mesh removal (partial or total) was required. The mean follow-up length was 42.4 months (1 – 102).

Conclusion: All 91 patients who underwent AWR with and without active infection and/or contamination, the TIGR Matrix Surgical Mesh was used. In this group patients there were no mesh related complications and no mesh removals required. Long-term follow-up > 3 years demonstrated the durability of the repair with TIGR Matrix in a TAR approach for AWR.

VIII. CONCLUSION

The TIGR Matrix Surgical Mesh and its primary predicate (K161424) have the same intended use and similar indications, technological characteristics and principles of operation. Minor differences between the subject device and the primary predicate do not present any new issues of safety or effectiveness. The TIGR Matrix Surgical Mesh is the same device as the reference predicate (K163005) with only minor differences in the indication for use to add hernia repair as part of soft tissue repair and removal of a contraindication to match the primary predicate's labeling, as supported by the preclinical and clinical performance testing. The TIGR Matrix Surgical Mesh is substantially equivalent to the primary predicate (K161424).