

K092224

Page 1 of 2

510(k) Summary

Submitter's Information:

JAN 25 2010

Name: Novus Scientific Pte Ltd
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Phone: +65 68900360
Contact Person: Kelvin Koh

Date of Preparation: 17 July 2009

Device Name:
Trade Name: TIGR Matrix Surgical Mesh
Common Name: Surgical Mesh
Classification Name: Mesh, Surgical, Polymeric
Classification Product Code: FTL
Regulatory number: §878.3300

Predicate Device Names: Prolene Mesh (K001122)
Mersilene Mesh (K851086)
Ultrapro Mesh (K033337)

Device Description:

TIGR Matrix Surgical Mesh is knitted from two different synthetic resorbable fibers, possessing different degradation characteristics. The first fiber, making up 40% of the matrix by weight, is a copolymer of polyglycolide, polylactide, and polytrimethylene carbonate.

The second fiber, making up 60% of the matrix by weight, is a copolymer of polylactide, and polytrimethylene carbonate. Both fibers degrade by bulk hydrolysis once implanted, resulting in a decreasing strength retention followed by mass loss of the fibers.

Based on the product's absorption characteristics, in vitro testing showed that the first fiber (polyglycolide, polylactide, and polytrimethylene carbonate) loses its functional capabilities after 2 weeks and in vivo studies in the abdominal wall of sheep showed that the first fiber was fully absorbed after 4 months. The same in vitro testing showed that the second fiber (polylactide, and polytrimethylene carbonate) loses its functional capabilities after 9 months and in vivo studies in the abdominal wall of sheep indicated that the second fiber should be absorbed after approximately 36 months.

Intended Use:

TIGR Matrix Surgical Mesh is intended for use in reinforcement of soft tissue where weakness exists.

Technological Characteristics:

The physical and mechanical properties of the TIGR Matrix Surgical Mesh, such as mesh thickness, density, pore diameter, mesh knit characteristics, suture retention strength, tear strength and burst strength, has similar performance characteristics to the currently marketed predicate devices.

Performance data:

The biocompatibility and safety tests conducted for TIGR Matrix Surgical Mesh were selected in accordance with "ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." All studies were conducted in accordance to 21 CFR, Part 58, Good Laboratory Practices. Based on the results from these studies, TIGR Matrix Surgical Mesh is considered to be non-toxic, nonmutagenic, non-sensitizing, biocompatible and safe for its intended use.

The effectiveness of TIGR Matrix Surgical Mesh was compared *in vivo* in a Sheep hernia repair model to the Prolene Mesh. The overall performance of TIGR Matrix Surgical Mesh, including tissue integration, local tolerance was equivalent to its predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Novus Scientific, Pte, Ltd.
% Mr. Kelvin Koh
Nordic European Centre
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Singapore 609927

JAN 25 2010

Re: K092224
Trade/Device Name: TIGR Matrix Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh, Polymeric
Regulatory Class: Class II
Product Code: FTL
Dated: November 18, 2009
Received: November 23, 2009

Dear Mr. Koh:

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. 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.

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); good manufacturing practice requirements as set

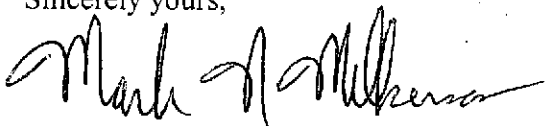
Page 2 – Mr. Kelvin Koh

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092224

Indications for Use

510(k) Number: K092224

Device Name: TIGR Matrix Surgical Mesh

Indications for Use:

TIGR™ Matrix Surgical Mesh is indicated for use in reinforcement of soft tissue where weakness exists.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092224