April 30, 2018

Proxy Biomedical Ltd.
% Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082

Re: K172636
Trade/Device Name: VitaMESH Macroporous PP Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 26, 2018
Received: March 27, 2018

Dear Elaine Duncan:

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. 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); good manufacturing practice requirements as set 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K172636

Device Name
VITAMESH™ MacroPorous PP Surgical Mesh

Indications for Use *(Describe)*
Proxy Biomedical VITAMESH™ surgical mesh is intended to assist in the repair and/or reinforcement of hernia and other fascial defects requiring the additional support of a nonabsorbable implant during and after wound healing

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.

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510(k) SUMMARY

SUBMITTER:

Submitted on behalf of:

Proxy Biomedical Ltd.
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Contact Person	Adrienne Tierney
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by: **Elaine Duncan, M.S.M.E., RAC**
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CONTACT PERSON for SUBMISSION: **Elaine Duncan**

DATE PREPARED: **August 29, 2017**

Device Trade Name	VitaMESH™ Macroporous PP Surgical Mesh
Common Name	Surgical Mesh
Classification reference	21 CFR 878.3300
Regulatory Class	II
Product Code	FTL
Predicate Device Name	VitaMESH™ Macroporous PP Surgical Mesh
Device 510(k) number	K060520

DEVICE DESCRIPTION:

The basis for this Traditional 510(k) submission is a material supplier change to the VitaMESH™ Macroporous PP Surgical Mesh. The synthetic mesh is constructed of knitted filaments of an alternative polypropylene resin. This material change does not affect the device description (or the device description on the package and instructions for use.) The proposed VitaMESH™ with the material supplier change is knitted by the same process as the predicate VitaMESH™, which interlinks each fiber junction and which provides for elasticity in both directions are.

INDICATION FOR USE:

VitaMESH™ Macroporous PP Surgical Mesh is intended to assist in the repair and/or reinforcement of hernia and other fascial defects requiring the additional support of a nonabsorbable implant during and after wound healing.

510(k) SUMMARY

BASIS FOR SUBSTANTIAL EQUIVALENCE **K172636, pg. 2 of 4**

The predicate VitaMESH™ Macroporous PP Surgical Mesh which was cleared under 510(k) number K060520 is a non-absorbable, synthetic mesh, constructed of knitted filaments of polypropylene. As shown in this submission, the VitaMESH™ with the resin change is the same product as the predicate. The following demonstrates substantial equivalence.

Comparison of VitaMESH™ with alternative material device to predicate device

Characteristic	**VitaMESH™**	**VitaMESH™**
	Proposed	Predicate
510(K)	K172636	K060520
Material: Chemically, Physically, and Biologically equivalent.	Alternative Polypropylene	Polypropylene

- There have been no changes made to the fiber extrusion process.
- No changes have been made to the manufacturing process (including sterilization) of the finished mesh device.
- There is no change to the proposed clinical use of the device.
- No changes have been made to the sterilization method of this device.
- There is no change to the packaging shelf life qualification as a result of this material change to VitaMESH™.
- The product catalogue range has increased since the original VitaMESH™ submission. The current product sizes are still within the original range of the predicate. . Minor changes to the packaging and labelling since the original submission for the predicate are unrelated to the material change and are summarized in the submission for information only

PERFORMANCE DATA:

The proposed VitaMESH™ has been manufactured with an alternative polypropylene resin to the predicate VitaMESH™ cleared under 510(k) number K060520. This alternative polypropylene has been shown to be substantial equivalent to the polypropylene used in the manufacturing of the predicate. This change was necessitated by the discontinuation of the original raw material polypropylene resin by the supplier. The following evaluations were provided in support of the substantial equivalence determination:

510(k) SUMMARY

Mechanical testing: The change of polypropylene used for manufacturing of VitaMESH™ does not introduce new risks to mechanical performance as shown by testing. All device specifications for the proposed VitaMESH™ are the same as for the predicate VitaMESH™. Mechanical testing and visual performance testing was performed on VitaMESH™ units manufactured using an alternative polypropylene resin to the predicate. This testing included:

- Aerial density
- Device stiffness
- Tensile strength
- Suture pullout strength
- Tear resistance
- Burst strength
- Pore size
- Mesh thickness
- Surface finish inspection

For product shelf life qualification, an aging study demonstrates that VitaMESH™ manufactured with the alternative polypropylene continues to meet specifications after 5 years accelerated aging both in physical characterization and performance testing. Additionally, a 5 year Real time aging study is in progress to support the above data.

Ethylene Oxide Residual Analysis: Ethylene oxide and ethylene chlorohydrin levels were found to be within limits specified in I.S. EN ISO 10993-7: 2008 'Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals (ISO 10993-7: 2008)'.

Microbiological Testing: A microbiological evaluation was conducted to mitigate against any risks identified in changing from the fibre extruded with the original polypropylene of the predicate to the alternative polypropylene. Bioburden testing carried out on the VitaMESH™ devices manufactured with the alternative polypropylene met Proxy Biomedical Ltd. acceptance criteria. Routine pyrogen testing carried out on the VitaMESH™ devices manufactured with the alternative polypropylene using Linulus Amoebocyte Lysate (LAL) method met all acceptance criteria.

Biocompatibility testing: The change of polypropylene used for manufacturing of the device does not introduce new risks to biological safety. Conformance with biocompatibility requirements is shown in this submission.

The biocompatibility evaluation for the VitaMESH™ Macroporous PP Surgical Mesh manufactured using an alternative polypropylene resin to the predicate was conducted in accordance with I.S. EN

510(k) SUMMARY

ISO 10993-1: 2009 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process'. Testing included Cytotoxicity, irritation, sensitization, and chemical characterization of alternative polypropylene resin..

Chemical analysis: Testing demonstrated comparable chemical constitution.

CONCLUSIONS:

Mechanical test data and the determination of biocompatibility as well as chemical characterization demonstrates that the VitaMESH™ Macroporous PP Surgical Mesh manufactured using the alternative polypropylene performs as intended use conditions. In additon, VitaMESH™ devices manufactured using the alternative polypropylene proposed in this submission is substantially equivalent to the predicate device.