DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 9, 2017

IconLab Inc.
% Mr. Anil Bhalani
RA Consultant
Extomed, LLC
24261 Lysanda Drive
Mission Viejo, California 92691

Re: K170134
Trade/Device Name: Reperen® Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: July 11, 2017
Received: July 11, 2017

Dear Mr. Bhalani:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170134

Device Name

Reperen® Surgical Mesh

Indications for Use *(Describe)*

The Reperen® Surgical Mesh is indicated for use in the reconstruction of hernias, soft tissue deficiencies and temporary bridging of fascial defects.

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
(K170134)

Reperen® Surgical Mesh

Applicant: IconLab Inc.
65 Enterprise
Aliso Viejo, CA 92656

Company Contact: Anil Bhalani
RA Consultant
ExtoMed, LLC
Phone: 949-596-9001
Email: anilbhalani@outlook.com

Date Summary Prepared: August 7, 2017

Trade Name: *Reperen*® Surgical Mesh

Common/Classification Name: Surgical Mesh, Class II

Regulation Number/Name: 21 CFR §878.3300, Surgical Mesh

Review Panel: General and Plastic Surgery

Product Code: FTL

Substantially Equivalent Device: GORE® DUALMESH® BIOMATERIAL (K992189)

Device Description:

The *Reperen*® Surgical Mesh is made from a biocompatible, hydrophobic acrylic polymer. The implant has two distinct layers: 1st layer is a smooth transparent film of spatially cross-linked acrylic polymer with polyamide mesh embedded inside. The 2nd layer is a mesh of spatially cross-linked acrylic polymer, interconnected forming the rough surface. The thickness of the reinforcing layer (in the total thickness of the Reperen® Surgical Mesh) is 0.1 + 0.05 mm. The roughness of the parietal layer for Reperen® Surgical Mesh (all sizes) is about 100 µm.

The Reperen® Surgical Mesh is available in six different sizes as described in the table below.

	Designation	Shape	Size in mm ± 3 mm	Thickness in mm, ± 0.15 mm	Weight in gm ±20%
1.	Reperen®-15-150-100	oval	150 x 100	0.4	5.4
2.	Reperen®-15-200-150		200 x 150	0.4	10.8
3.	Reperen®-15-250-150		250 x 150	0.4	13.5
4.	Reperen®-15-250-200		250 x 200	0.4	18.0
5.	Reperen®-15-300-200		300 x 200	0.4	21.6
6.	Reperen®-15-370-280		370 x 280	0.4	37.2

Indications for Use:
The Reperen® Surgical Mesh is indicated for use in the reconstruction of hernias, soft tissue deficiencies and temporary bridging of fascial defects.

Contraindications:
Not for reconstruction of cardiovascular defects. Use of this product in applications other than those indicated has the potential for serious complications, such as aneurysm formation or undesired healing to surrounding tissues.

- Do not use in patients during growth (childhood, pregnancy)
- Do not use in the presence of undeleted foreign bodies in the wound, the presence of signs of purulent infection (contaminated wounds)
- Do not use with uncontrolled and/or active bleeding
- Strangulated hernia with evidence of necrotic changes in the internal organs of the abdominal cavity
- Hypoproteinemia (cancer, cirrhosis)

Intended Use:
The Reperen® Surgical Mesh is indicated for use in the reconstruction of hernias, soft tissue deficiencies and temporary bridging of fascial defects. It is not intended to be used for the reconstruction of cardiovascular defects.

Performance Data Summary:
The *Reperen*® Surgical Mesh was subjected to applicable performance/product characterization testing and biocompatibility testing requirements described in the FDA Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (Document issued on March 2, 1999) to determine substantial equivalence to its predicate devices. The *Reperen*® Surgical Mesh met all specified design and performance requirements.

Performance Testing included the following tests.

- Mesh Thickness
- Mesh Density
- Suture Retention Strength
- Tear Resistance
- Uniaxial Tensile Stress
- Ball Burst Testing
- Mesh Stiffness

Biocompatibility Testing was performed per 10993-1 and included the following tests.

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous reactivity
- Systemic toxicity (acute)
- Subchronic Toxicity
- Genotoxicity
- Implantation (with histology of the surrounding tissue)
- Hemolysis
- Pyrogenicity
- Chemical Characterization Studies

Animal Studies
In vivo porcine studies were performed to characterize the mechanical strength, tissue response and clinical efficacy in comparison to the predicate device. The results demonstrate that the Reperen® Surgical Mesh performance is substantially equivalent to the predicate.

Voluntary Safety and International Agency Standards:
The following voluntary and international agency standards and guidelines were reviewed and are followed in the development of the *Reperen*® Surgical Mesh to ensure its safety and suitability for its intended use:

- ISO 11135 Second Edition 2014, Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- AAMI / ANSI / ISO 10993-7:2008(R) 2012, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.
- ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

Substantial Equivalence: The technological differences between the *Reperen*® Surgical Mesh and the predicate device, GORE® DUALMESH® BIOMATERIAL (K992189) do not raise new questions of safety or effectiveness.

Conclusion:
Information in the 510(k) submission demonstrates that the *Reperen*® Surgical Mesh is substantially equivalent to its predicate device.