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

October 20, 2016

LiVac Pty Ltd
% Mr. Stuart R. Goldman
Emergo Global Consulting LLC
2500 Bee Cave, Building 1, Suite 300
Austin, Texas 78746

Re: K162445
Trade/Device Name: LiVac Retractor System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 1, 2016
Received: August 31, 2016

Dear Mr. Goldman:

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 801and Part 809); 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 and Part 809), 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 yours,

Jennifer R. Stevenson -A

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

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)*

K162445

Device Name
LiVac Retractor System

Indications for Use *(Describe)*

The LiVac Retractor is designed as an organ and tissue retractor for use in laparoscopic procedures to elevate organs and tissue to provide improved access and visualisation of surgical sites.

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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Section 5 510(k) Summary

1. Submission sponsor

Submission sponsor	Livac Pty Ltd
Company Address	8 Melaleuca Court, Warrnambool VICTORIA 3280, Australia
Contact details	Dr Anabela Correia, CEO Phone +61 412003606 Email: anabela@livac.com.au

2. Submission correspondent

Submission correspondent	Emergo Global Consulting LLC 2500 Bee Cave, Bldg 1 Suite 300 Austin, Texas 78746 USA
Contact details	Stuart R. Goldman Senior Consultant Office: +1.512.327.9997 Email: projectmanagement@emergogroup.com

3. Date Prepared

Date Summary Prepared	August 1, 2016

4. Device Identification

Type of 510(k) Submission	Traditional
Trade or Proprietary Name	LiVac™ Retractor System (LiVac™)
Common or Usual Name	Retractor
Regulation Number	21 CFR 876.1500
Regulation Name	Endoscope and Accessories
Product Code	GCJ
Class of Device	Class II
Panel	General & Plastic Surgery

5. Legally Marketed Predicate Device

Reveel Endoscopic Retractor (K133345): Retraction Limited

6. Device Description

The LiVac Retractor System is a soft silicone ring connected to suction tubing and is designed to maintain apposition between two substantially planar, conformable, solid organ surfaces, most typically the diaphragm and either lobe of liver, or spleen, thereby exposing the organs beneath. The system is comprised of three components: 1.) LiVac Retractor, 2.) LiVac Bevel, and 3.) LiVac Connector.

The suction tubing is connected to a sterile suction hose via the connector, which is positioned partially within the abdominal wall. The LiVac Connector can lie alongside a 12-15mm port within the secondary channel of the LiVac Bevel as per Hasson technique, or within a single incision laparoscopic port device.

7. Indications for Use Statement

The LiVac Retractor is designed as an organ and tissue retractor for use in laparoscopic procedures to elevate organs and tissue to provide improved access and visualisation of surgical sites.

8. Substantial Equivalence Discussion

The following table compares the LiVac Retractor to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities and differences to the predicate device.

Table 1 Substantial Equivalence Comparison Table

Device Name	**LiVac Retractor System**	**Reveel Endoscopic Retractor**	**Similarities/Differences**
Device Sponsor	Livac Pty Ltd	Retraction Limited	-
510(k) No.	To be determined	K133345	-
Product Code	GCJ	GCJ	-
Classification Name	Laparoscope, general & plastic surgery	Laparoscope, general & plastic surgery	Same
Device Class	II	II	Same
Regulation No.	876.1500	876.1500	Same
Regulation Description	Endoscope and accessories	Endoscope and accessories	Same
Indications for Use	The LiVac Retractor is designed as an organ and tissue retractor for use in laparoscopic procedures to elevate organs and tissue to provide improved access and visualisation of surgical sites.	Reveel is designed as an organ and tissue retractor for the use in endoscopic procedures to elevate organs and tissues to provide better access as well as visualization of surgical sites.	Same
Prescription Use	Yes	Yes	Same

Device Name	LiVac Retractor System	Reveel Endoscopic Retractor	Similarities/Differences
Body Location	Abdominal	Abdominal	Same
Target Area	Liver and other organs and tissues.	Liver and other organs and tissues.	Same
Single Use	Yes	Yes	Same
Supplied Sterile	Yes (Gamma)	Yes (Gamma)	Same
Device Description	The LiVac Retractor is a soft silicone ring connected to suction tubing. The suction tubing is connected to a large calibre external (sterile) suction hose via the LiVac Connector. The LiVac Retractor can be used as a standalone device with a laparoscopic multi-channel single port or with a 12-15 mm laparoscopic port. The LiVac Bevel accessory is used to facilitate use of the LiVac Retractor with a 10-12 mm "Hasson" type port inserted at the umbilicus.	Reveel is a single use device intended for mobilizing and manoeuvring organs and tissue during endoscopic surgical procedures. It is comprised of a proximal handle, a rigid shaft and a distal retraction surface.	LiVac and Reveel are manufactured from different materials, and therefore their biological characteristics are different. LiVac and Reveel are used under the same conditions of use, but use different deployment methods and different principles of operation. They also have different specifications, properties and are different in design. Therefore there are some differences in their technical characteristics.
Mode of Operation or Technical Characteristics	Suction (negative pressure) applied to the device by an externally regulated suction source by way of a suction hose/adaptor in the facility; i.e., vacuum technology.	Manual (positive pressure) applied to the device by hand.	Following insertion into the abdominal cavity, the deployment methods are different: The LiVac Retractor lifts from above, whereas the Reveel Retractor pushes from below. The principles of operation are also different: LiVac uses objective regulated negative pressure, Reveel use subjective manual positive pressure.
Materials/Features/ Design Flexibility	Soft silicone ring connected to suction tubing. Optional accessory bevel (modified Hasson design). Both material and design are flexible. Rigid connector used through or alongside port.	Rigid metal central beam, with "harp" shaped retraction arm covered in high coefficient of friction composite material. Central shaft is inflexible, arms have two dimensional flexibility.	The LiVac Retractor is made of a soft silicone, while the Reveel Retractor is made from a rigid metal, and therefore the products have different specifications and properties.
Biocompatibility Testing	Per ISO 10993-1	Per ISO 10993-1	Similar
Sterilization Testing	Per ISO 11137-1 Per ISO 11737-1	Per ISO 11137-1	Similar
Shelf-Life Testing	Per ISO 11607-1	Not known	Not known

9. Performance Data – Bench

As part of demonstrating safety and effectiveness of the LiVac Retractor System, LiVac completed a number of tests on their device to demonstrate that it meets all design requirements for performance characteristics, biocompatibility, sterilization, shelf-life and risk. The LiVac Retractor System passed all testing in accordance with internal LiVac performance testing, as well as those international standards shown below to support substantial equivalence of the subject device.

- LiVac functional performance testing to demonstrate device retraction times: Pass
- Biocompatibility testing per ISO 10993 (Part 1, Part 5 and Part 10): Pass
- Sterilization validation per ISO 11137-1/-2/-3 and ISO 11737-1/-2: Pass
- Packaging and Shelf-Life per ISO 11607-1/-2: Pass
- Risk Analysis per ISO 14971: Completed with all risk mitigated to as low as possible

10. Performance Data – Animal

Livac conducted three non-clinical studies on pigs to evaluate the LiVac Retractor in laparoscopic surgery at the University of Melbourne (Australia), School of Veterinary Science - Animal laboratory. These studies demonstrated use of the LiVac Retractor in cholecystectomy and gastrectomy procedures. A fourth study was conducted by an independent surgeon in Italy. The LiVac retractor was successfully used for a cholecystectomy. The maximum pressure used was -500 mmHg.

11. Performance Data – Clinical

Livac conducted an open label study of the performance and safety of the LiVac Retractor in laparoscopic surgery at two hospitals in Victoria, Australia. The study was conducted in accordance with ISO 14155-2011. The primary objective of the study was to evaluate the performance of the LiVac Retractor in patients undergoing upper abdominal single or multi-port laparoscopic surgery, while the secondary objectives of the study were to evaluate the safety and tolerability of the LiVac Retractor; to evaluate the performance of the LiVac Bevel accessory to the LiVac Retractor, used in multiport procedures; and to evaluate the safety and tolerability of the LiVac Bevel used in multiport procedures.

The study provides evidence for the performance and safety of the LiVac Retractor and demonstrates that the use of the LiVac Retractor does not raise new questions of safety or effectiveness. Both primary and secondary performance objectives were achieved. Both primary and secondary safety objectives were achieved. No new risks were identified.

12. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device or the device has the same intended use and different technological characteristics provided it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device. The LiVac Retractor System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device, the Reveel Endoscopic Retractor (K133345), manufactured by Retraction Limited.