APR 1 1 2014

## 510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of CFR 807.92

1. **SUBMITTER INFORMATION**

| | |
|---|---|
| a. Company Name: | RETRACTION LIMITED |
| b. Company Address: | Unit F, 2/F,<br>Hong Kong Industrial Building,<br>444-452 Des Voeux Road West,<br>Hong Kong |
| c. Telephone:<br>Fax: | +852 3110 6011<br>+852 2168 4120 |
| d. Contact Person: | Stuart Moran<br>Chief Executive Officer |
| e. Date Summary Prepared: | 2013-10-28 |

2. **DEVICE IDENTIFICATION**

| | |
|---|---|
| a. Trade/Proprietary Name: | REVEEL ENDOSCOPIC RETRACTOR |
| b. Common Name: | Retractor |
| c. Classification Name: | Laparoscope, General and Plastic Surgery: Endoscope and accessories (21 CFR 876.1500, Product Code GCJ) |

3. **IDENTIFICATION OF PREDICATE DEVICES**

| | | |
|---|---|---|
| PRETZELFLEX | Surgical Innovations Limited (K123110) | ***"PRETZELFLEX"*** |
| AUTO SUTURE ENDO RETRACT II | United States Surgical (Covidien) (K914190) | ***"ENDO RETRACT II"*** |
| RETRACTOR | Automated Medical Products Corp. (K942002) | ***"NATHANSON"*** |

**4. DESCRIPTION OF THE DEVICE**

REVEEL is a single use device intended for mobilizing and maneuvering organs and tissue during endoscopic surgical procedures. It is comprised of a proximal handle, a rigid shaft, and a distal retraction surface.

**5. STATEMENT OF INTENDED USE**

REVEEL is designed as an organ and tissue retractor for the use in endoscopic surgical procedures to elevate organs and tissue to provide better access as well as visualization of surgical sites

**6. TECHNOLOGICAL CHARACTERISTICS COMPARISON WITH PREDICATE DEVICES**

The REVEEL ENDOSCOPIC RETRACTOR is substantially equivalent to the PRETZELFLEX, ENDO RETRACT II, and NATHANSON in terms of the sterilization method, packaging, product architecture, retraction surface, patient contact materials, mechanism of operation, method of insertion, incision site and incision size.

**7. NON CLINICAL TESTS SUMMARY**

The device has been subjected to bench testing; simulated transportation testing; simulated shelf life testing; sterilization validation; and biocompatibility testing, in order to ensure that the device performs as intended when used in accordance with its instructions for use.

**8 PRE-CLINICAL TESTS SUMMARY**

The use of porcine and cadaveric models demonstrates through real life simulation that the REVEEL ENDOSCOPIC RETRACTOR is capable of functioning as intended; such as insertion, actuation, device mobilization and retraction, visualization of gastroesophageal junction, device de-actuation and removal.

**9 CONCLUSION**

The results of bench and pre clinical testing demonstrate that the REVEEL ENDOSCOPIC RETRACTOR is as safe and effective as the identified legally marketed predicate devices for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

RETRACTION LIMITED
Mr. Stuart Moran
Chief Executive Officer
Unit F, 2/F, Hong Kong Industrial Building
444-452 Des Voeux Road West
Sai Wan, 999077
HONG KONG

Re: K133345
Trade/Device Name: REVEEL ENDOSCOPIC RETRACTOR
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 19, 2014
Received: February 24, 2014

Dear Mr. Moran:

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): Not known K133345

Device Name: REVEEL ENDOSCOPIC RETRACTOR

Indications For Use:

REVEEL is designed as an organ and tissue retractor for the use in endoscopic surgical procedures to elevate organs and tissue to provide better access as well as visualization of surgical sites.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S