



Food and Drug Administration
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April 19, 2016

LumenR, LLC
% Joseph Azary
Consultant
Joseph Azary
543 Long Hill Avenue
Shelton, CT 06484

Re: K153698
Trade/Device Name: LumenR Tissue Retractor System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: ODB, FED, GAD
Dated: March 8, 2016
Received: March 16, 2016

Dear Joseph Azary,

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 yours,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)

K153698

Device Name
LumenR Tissue Retractor System

Indications for Use (Describe)

The LumenR Tissue Retractor System is indicated for use in conjunction with an endoscope for tissue or foreign body manipulation and/or where multiple removal and reinsertions of the endoscope are required.

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
for LumenR, LLC
LumenR Tissue Retractor System**

1. SUBMITTER/510(K) HOLDER

LumenR, LLC
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Matawan, NJ 07747

Contact Name: Joseph Azary
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Date Prepared: December 21, 2015

Date Revised: April 19, 2016

FDA Registration# 3009540718

2. DEVICE NAME

Classification Name: Endoscopic Contamination Prevention Sheath
Retractor, Manual Surgical Instrument
Classification Regulation: 21 CFR 876.1500, 21 CFR 878.4800
Product code: ODB
GAD
FED
Classification: Class 2
Medical Specialty (Panel): General Surgery Devices, Gastro-enterology

3. PREDICATE DEVICES

- Megachannel Endoscopic Overtube - K080550

4. DEVICE DESCRIPTION

The LumenR Tissue Retractor System (LRS) is an intra-luminal surgical device facilitating tissue manipulations inside the lumen.. It is a non-powered, hand-manipulated device.

The LumenR Tissue Retractor System includes a LumenR Instrument Guide

(LIG) and LumenR Cannula Retractor (LCR).

The LIG and LCR are single use devices that are provided non-sterile.

LumenR Cannula Retractor (LCR) is provided in various Lengths and Diameters in order to accommodate individually variable natural body lumens.

The LumenR Cannula Retractor (LCR) comprises of (1) Handle (proximal end located outside of a patient), (2) Retractor (chamber-like expandable retractor located at the device's distal end), and (3) flexible Shaft (located in between the handle and a Retractor).

(1) **LCR Handle** is a substantially cylindrical structure, interfacing operator's hands and located outside of a patient. The Handle has:

- a- **Retractor Slider**, which slides forward and backward to correspondingly either expand (retract more) or collapse (retract less) the distally located LCR Retractor. The Retractor facilitates tissue retraction and tissue manipulations inside the gastro-intestinal lumen. The Retractor Slider is activated by the operator's hand.
- b- **Insufflation port** for attachment to an insufflation tubing, allowing to use additional insufflation during the procedure.
- c- **Ancillary port openings** – one or two openings where the LumenR Instrument Guides (LIGs) can be inserted into the LCR to reach the working space formed by the LCR Retractor. The seal, located inside the Ancillary port, reduces the gas leakage from the lumen around the LIG.
- d- **Endoscope channel opening** is an opening for a standard endoscope. Endoscope is inserted into the LCR Endoscopic channel – via Endoscopic channel opening - to reach the working space formed by the LCR Retractor. Endoscopic channel opening has a seal reducing the gas leakage from the lumen around the endoscope.

(2) **LCR Retractor** is located at the distal end of the LCR Shaft, which is inserted inside a gastrointestinal lumen, during the procedure The Retractor includes:

- a- **Retractor wire structure** is actuated at the LCR Handle by moving Retractor Slider forward (Retractor expands) or backward (Retractors collapses) to adjust the working space inside the Retractor.. When Retractor Slider is moved forward on the LCR Handle, the two top retractor wires of the Retractor wire structure are arched laterally, thus expanding the LCR Retractor and the associated working space.

- b- Plastic cover or “Basket”** is the outer plastic layer, which forms a translucent cover around the Retractor wire structure. The main purpose of the Plastic cover is to provide a protective layer around the Retractor wire structure during the device delivery and to minimize the protrusion of the luminal walls into the working space during procedure. In addition, the Plastic cover helps protect the luminal walls during the procedure from the accidental injury by the conventional instruments. Furthermore, the plastic cover can facilitate the specimen containment and retrieval.
- c- Distal Cap** is located at the distal aspect of the LCR Retractor, which contains the distal ends of the Retractor wire structure. The Distal Cap has a central opening for the endoscope, enabling the over-the-scope delivery of the device to the target site.
- d- Proximal Cap** is located at the proximal aspect of the LCR Retractor, which contains the proximal ends of the Retractor wire structure. It also has an opening for the endoscope as well as 1 or 2 additional openings for the LIGs.

(3) **LCR Shaft** is a flexible conduit, having Endoscopic channel (a channel for the endoscope) and 1 or 2 Ancillary (LIG) channel(s).

The LCR Shaft is designed to provide:

- a-** Support to the LCR Retractor,
- b-** Flexibility to improve pass-ability
- c-** Torsional stiffness for rotation positioning of the LCR Retractor within the lumen,
- d-** Column strength for advancing the LCR Retractor over the endoscope,
- e-** Tensile strength for removal of the LCR Retractor over the endoscope.

LumenR Instrument Guide (LIG) is an instrument guide or a hollow conduit for existing flexible endoscopic instruments, for example, tissue forceps, which helps guide the instrument towards the target tissue, but doesn't directly interact with the tissues.

The LIG is inserted into the Ancillary (LIG) Port and advanced inside LCR Shaft until it reaches the working space formed by the LCR Retractor. The LIG has two primary degrees of freedom: longitudinal (forward-backward) and rotational movements.

LumenR Instrument Guide (LIG) is provided in different diameters, lengths, and angles in order to accommodate individual anatomical variations. For example, for a narrower lumen, an operator may select to use LIG with a smaller - 45 degrees - angle to better maneuver inside the working space.

The LIG comprises of: (1) Tip structure, (2) Shaft, and (3) Handle.

- (1) **LIG Tip** is a flexible pre-bent (angled) distal end of the LIG, allowing LIG to be delivered to the LCR Retractor space via substantially straight LIG channel of the LCR. When the LIG Tip enters the working space of the LCR Retractor from the LIG channel, it returns to its originally angled shape. A flexible endoscopic instrument, for example, a tissue forceps, when inserted into the LIG with a described angled tip, can be better controlled and guided towards the target site.

- (2) **LIG Handle** is a cylindrical structure for handling the LIG during the procedure. It has a proximal opening with a valve preventing an air leak from the working space. This opening can receive a standard endoscopic instrument, for example a tissue forceps, of the appropriate size.

- (3) **LIG Shaft** is a flexible conduit connecting the LIG Tip and the LIG Handle. The shaft is longitudinally flexible and torsionally stiff, allowing an operator to control the LIG Tip inside a working space. The LIG Shaft also has LIG Marking indicating the position of the LIG Tip within the LCR.

Model	Diameter	Retractor	Working Length	# LCR Channels	LIG Channel Instrument Size Compatibility
LCR-60	25mm	Length 8cm Max height 6cm Max width 4.5cm	60cm	3	2.8mm
LCR-75S	18mm	Length 8cm Max height 6cm Max width 4.5cm	75cm	2	1.8mm
LCR-95	25mm	Length 8cm Max height 6cm Max width 4.5cm	95cm	3	2.8mm

5. INTENDED USE

The LumenR Tissue Retractor System is indicated for use in conjunction with an endoscope for tissue or foreign body manipulation and/or where multiple removal and reinsertions of the endoscope are required.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Megachannel (510k K080550) and LumenR Tissue Retractor System are substantially equivalent based on the following:

- Equivalent indications for use.
- Both devices are non-sterile.
- Both devices can accommodate an endoscope and instruments.
- Both devices are used in natural orifices for access to colon and esophagus.
- Dimensional similarities: LumenR LCR is available in OD between 18mm to 25mm OD, and length between 60cm - 95cm; Megachannel has OD of 22mm and length between 80cm – 100cm.
- The devices can accommodate similarly sized endoscopes: LumenR can accommodate 12.7mm OD endoscope, Megachannel can accommodate 12.8mm OD endoscope.
- The LumenR and Megachannel have similar insertion and removal force profiles during testing.
- Material Composition is similar. Both devices are composed of wire reinforced PVC and the guides/introducers are both composed of smooth thermoplastic.
- The LumenR devices are available with 2 and 3 small channels, whereas the Megachannel has 1 large channel. The Megachannel allows both a scope and instruments to be inserted together into a single larger channel.

One of the main differences between the LumenR and Megachannel is that

LumenR has a retractor function, which helps retract the target tissue, facilitating the access and visibility of the endoscopic instruments to the surgical site. In addition, the LumenR has 2 or 3 small channels inside the main shaft for an endoscope and accessory instruments, allowing them to operate independently from each other. Since Megachannel has only one large channel, the endoscope and the accessory instruments may interfere with each other during a procedure.

7. PERFORMANCE TESTING

The subject device conforms to the following standards:

- ASTM F088/ASTM F088M-09 Standard Test Method for Seal Strength of Flexible Materials
- ASTM D3078-02 Standard Test Method for Determination for Leaks in Flexible Packaging by Bubble Emission
- ASTM F1980-02 Standard Guide for Accelerated Aging of Sterile Medical Device Packaging
- ASTM D4169-09 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices, Part 5: Test for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization

8. SAFETY AND EFFICACY

The subject device was subjected to testing including:

- Biocompatibility Testing
- Shipping and Packaging Testing
 - Simulated distribution
 - Box integrity study
 - Bag leak test
 - Product integrity testing
 - Seal Peel Strength
- Comparison Testing to Predicate Device
- Microbial Limits Testing
 - Microbial Enumeration Test
 - Test for Specified Microorganisms
- Performance Testing / Shelf Life Study including:
 - Tensile Strength
 - Reliability Cyclic

- Bending Reliability
- Break Strength
- Reliability Stress Testing of the Tip
- Leak Testing (seal around endoscope)

9. CONCLUSION

LumenR, LLC believes that based on the indications for use, technological characteristics, and comparison to predicate devices the LumenR Tissue Retractor System has been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.