



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

June 23, 2016

ITL Corporation Pty Ltd  
% Ms. Emily Rossiter  
President  
Regulatory Resources, Inc.  
276 William Way  
Williamsburg, Virginia 23185

Re: K153472

Trade/Device Name: Quiver Laparoscopic Extendable  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: HAM  
Dated: November 30, 2015  
Received: December 2, 2015

Dear Ms. Rossiter:

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,

**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)

K153472

Device Name

Quiver Laparoscopic Extendable

Indications for Use (Describe)

Holder for electrosurgical diathermy system conducting unit and/or other long instruments during surgery. For single-use only.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

22-Jun-16



## 510(k) Notification For QUIVER LAPAROSCOPIC EXTENDABLE (A100604)

### 5: 510k Summary

**5.1 510k Submitter, Sponsor & Owner:** ITL Corporation Pty Ltd  
1/63 Wells Road, Chelsea Heights  
Victoria, Australian Capital Territory, 3196  
Australia  
Phone: 61-3-8773-3050  
Fax: 61-3-8773-3059

**5.2 Contact Person:** Emily B. Rossiter  
President, Regulatory Resources, Inc.  
Registered Agent for ITL  
276 William Way  
Williamsburg, VA 23185  
[rri@infionline.net](mailto:rri@infionline.net)  
Phone: 804-370-9459  
Fax: 757-277-0212

**5.3 Date of Summary:** June 22, 2016

#### 5.4 Device

5.4.1 Trade Name: Quiver Laparoscopic Extendable

5.4.2 Common or Usual Name: Laparoscopic Instrument Holder

5.4.3 Classification Name: Apparatus, Electrosurgical (Accessory) 21 CFR 878.4400

5.4.4 Regulatory Class : 2

5.4.5 Device Product Code: HAM

**5.5 Predicate Device:** Modified Olsen Disposable Holster, K884172  
This product has not been subject to a design-related recall.

**5.6 Device Description:** The Quiver Laparoscopic Extendable is a telescoping instrument holder comprised of two separate parts. One component (the outer or top component) has two open ends and the other component has one open end and one closed end. It is provided assembled and sterile, allowing compact storage and shipment then extension by the user to hold long surgical instruments. After use, the device can be collapsed for compact disposal. A loop handle attached to the top can be used for hanging the device in a convenient place.

22-Jun-16

**5.7 Indications for Use:** Holder for electrosurgical diathermy system conducting unit and/or other long instruments during surgery. For single use only.

**5.8 Comparison of Technological Characteristics with the Predicate Device:**

Both holders are simple non-active containers made of disposable material with stiffness and thermal resistance properties suitable for heat-conducting surgical instruments. The Modified Olsen Holster is rectangular in shape with rounded corners and a lid; its length is 6¼ inches. The Quiver Laparoscopic Extendable is cylindrical in shape with a loop on the top of the holder that can function as a hanger. It has no lid. Its length is approximately 9½ inches collapsed and 15¾ inches extended. The two holders have a top opening of similar size for insertion of instruments. Neither holder is intended for patient contact.

**5.9 Performance Data:** The Quiver Laparoscopic Extendable is made of material that has been tested for hemocompatibility, cytotoxicity, sensitization, irritation and systemic injection although the Quiver is not a patient contact device. The device has undergone evaluation and testing that includes:

- Visual inspection and dimensional measurement of all moulded components
- Full assembly physical inspection and measurement
- Extension/Collapsing Test
- Application Test
- In-house Drop Test
- Packaging Integrity Test
- Accelerated aging test (real time aging test ongoing)

The ETO sterilization method for the Quiver Laparoscopic Extendable has been validated according to ISO 11135:2007 Sterilization of Health Care Products with SAL specification  $10^{-6}$ .

**5.10 Conclusions:** Quiver Laparoscopic Extendable is substantially equivalent to the predicate device, as both have the same intended use and functional characteristics. Any safety or effectiveness concerns arising from differences between the two devices have been addressed through performance testing. A risk evaluation of the Quiver Laparoscopic Extendable has been conducted in accordance with EN ISO 14971:2012, Application of Risk Management to Medical Devices, and EN 62366:2008, Usability Engineering File. Mitigation measures have been defined and implemented for all potential risks identified to date that are associated with the design, usability, manufacturing, storage and intended use of the device.