DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 1, 2015

TAIWAN SURGICAL CORPORATION
Ms. Celine Haung
Regulatory Specialist
3F., No.12, Sec.2, Sheng Yi Road
Zhubei City
Hsinchu County 30261
Taiwan

Re: K150253
Trade/Device Name: Disposable Suction Irrigation, 330mm,
Disposable Suction Irrigation, 450mm
Regulation Number: 21CFR 876.1500
Regulation Name: Endoscope & Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 4, 2015
Received: February 6, 2015

Dear Ms. Haung:

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" (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,

Jennifer R. Stevenson -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)*
K150253

Device Name
Disposable Suction Irrigation, 330mm
Disposable Suction Irrigation, 450mm

Indications for Use *(Describe)*
Suction Irrigation is indicated for general purpose use as suction/irrigation device to facilitate lavage during laparoscopic surgery and general surgery. The device functions to aid flushing blood and tissue debris from the surgical site.

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

The assigned 510(K) number: ____K150253_____

Date Prepared: 1/30/2015

I. SUBMITTER

Submitter:

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II. DEVICE

Trade Name:

- Disposable Suction Irrigation, 330mm
- Disposable Suction Irrigation, 450mm

Common Name and Classification:

Table 1. Common Name and Classification

No.	Common Name	Product Code	Classification	Regulation Section	Panel
1	Disposable Suction Irrigation	GCJ	II	876.1500	Endoscope and accessories

III. PREDICATE DEVICE

Predicate device 1: UNIMAX MEDICAL SYSTEM INC., K103509

Table 2. Predicate Device Identification

Subject Device	Predicate Device		
	Predicate Device	**Manufacturer**	**510(k) Number**
Disposable Suction Irrigation	UNIMAX SUCTION IRRIGATION SET	UNIMAX	K103509

IV. DEVICE DESCRIPTION

The suction irrigation set, consists of a hand piece equipped with two trumpet style valves, a probe, and connecting lines of tubing, one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure.

The suction irrigation set is designed to deliver-sterile irrigation fluids to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris, and smoke from the surgical site while the hand piece of the suction irrigator is designed to allow instruments to be introduced through the suction irrigation probe to reach the operative site. The instrument adapter is adjustable to allow a variety of instruments and diameters. It is a single use, disposable device and is sold sterile.

V. INDICATIONS FOR USE

Suction Irrigation is indicated for general purpose use as suction irrigation device to facilitate lavage during laparoscopic surgery and general surgery. The device functions to aid flushing blood and tissue debris from the surgical site.

VI. PRODUCT SPECIFICATION

Suction irrigation consists of a hand piece equipped with two trumpet style valves, a probe, and connecting lines of tubing, one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an inspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure. For Model TSI-545, the length of the stainless steel tube is 450mm while the length of the stainless steel tube is 330mm for Model TSI-533. The irrigation pressure is from 0 to 760mmHg while the suction pressure is from 0 to 600mmHg.

VII. COMPARISION OF TECHNOLOGY CHARACTERISTICS WITH THE PRIDICATE DEVICE

Table 3. Specification comparison table

Item			Candidate Device	Predicate Device
			Disposable Suction Irrigation	Unimax Suction Irrigation Set
1	Spec.	Design Description	Suction irrigation consists of a hand piece equipped with two trumpet style valves, a probe, and connecting lines of tubing, one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an inspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure.	Same
		Length of steel tube	350mm/470mm	350mm/470mm
		OD of steel tube	5mm	Same
		PVC soft tube	2900mm	2900mm
2	Function	Anti-vacuity test	Pass	Pass
		Anti-flat tube test	No flat tube	No flat tube
		Handle button pressure test	760 mmHg	760 mmHg

3	Biocompatibility		Cytotoxicity Test Intracutaneous test Maximization sensitization test	Same
4	Regulatory	Classification	class II	Same
			876.1500	Same
		Intended Use	Suction Irrigation is indicated for general purpose use as suction/irrigation device to facilitate lavage during laparoscopic gynecologic surgery, general surgery, thoracic surgery and urology. The device functions to aid flushing blood and tissue debris from the surgical site.	The Unimax Suction Irrigation Set is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.
5	Package		A pouches with protective cover	Same

VIII. PERFORMANCE DATA

- Biocompatibility summary：

  Because the stainless steel and Plasticized Polyvinyl Chloride Compound (PVC) are standard materials for current suction irrigation on the market, they have been thoroughly tested in the past for biocompatibility. The product has passed the biocompatibility test for cytotoxicity, intracutaneous irritation, skin sensitization, and pyrogen.by following ISO 10993.

  Therefore, as the contact time for the device is short (<24 hour) with the body and the biocompatibility has proved that device will not cause any cytotoxicity, intracutaneous irritation, skin sensitization, or pyrogen reaction to the body.

- Performance Testing summary：

  As the Bench report for Disposable Suction Irrigation concludes that：

  (1) Anti-Vacuity test：Unimax >TWSC. Therefore, the anti-vacuity capability of TWSC is the best: the second is Unimax.

  (2) Anti-flat tube test：Based on the experiment result, under the suction pressure between 400 and 760 mmHg, there is no flat tube situation.

  (3) Handle button pressure test：Based on the handle button pressure test and experiment result, the anti-pressure leak capability of is the worse; but the capability is correspond with product specification.

- **Sterilization and Bio Burden Test Summary：**

  The sterilization validation of gamma irradiation for Disposable Suction Irrigation was successful and had met the requirements of ISO 11137-2:2012 VD max25 method on substantiation of 25kGy as a sterilization dose. This study therefore supports the multiple batch products to be irradiated at the sterilization dose kGy for a SAL of 10^{-6}.

IX. CONCULSIONS

The Taiwan Surgical Disposable Suction Irrigation has the same intended use and same basic technology as the predicate device, thus is able to achieve same effectiveness and safety as the predicate device.