DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 11, 2017

Well Lead Medical Co., Ltd
Huang Kai gen
Regulatory Affairs Manager
C-4# Jinhu Industrial Estate, Hualong, Panyu
Guangzhou, Guangdong 511434
China

Re: K162340
Trade/Device Name: Stomach Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: September 13, 2017
Received: September 15, 2017

Dear Huang Kai gen:

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,

Joyce M. Whang -S

for

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)*
K162340

Device Name
Stomach Tube

Indications for Use *(Describe)*
The Stomach Tube is intended for gastric decompression. It is used to drain undesirable contents from the stomach, or decompress the stomach. The device is available in sizes 6Fr to 22Fr for use in adults 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.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	2017/10/10
Submitter:	WELL LEAD MEDICAL CO., LTD. Address:C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Contact Person:	Huang Kaigen Regulatory Affairs Manager WELL LEAD MEDICAL CO., LTD. Email: huangkg@welllead.com.cn Tel: +86-20-84758878 Fax:+86-20-84758224
Device Name:	Stomach Tube
Common Name:	Levin Tube
Regulation Number:	876.5980 Gastrointestinal tube and accessories
Classification Name:	Gastrointestinal tube and accessories
Product Code:	KNT
Regulatory Class:	Class II
Predicate Device(s):	K022112-All Silicone Stomach (Gastric) Tube

1. Intended Use

The Stomach Tube is intended for gastric decompression. It is used to drain undesirable contents from the stomach, or decompress the stomach. The device is available in sizes 6Fr to 22Fr for use in adults only.

2. Device Description

The Stomach Tube is a sterile, single-use tube manufactured in various sizes from medical grade PVC. The Stomach Tube is intended for gastric decompression. It is used to drain undesirable contents from the stomach, or decompress the stomach. The tube is inserted into a patient's stomach through the patient's nose or mouth.

The Stomach Tube is supplied in French size ranging from 6 to 22, consists of main tube and connector. The stomach tube connector connects to suction device for suctioning. The tube is available in open tip and closed tip form. It is composed of biologically safe materials and supplied sterile and intended for single use only.

3. Substantial Equivalence—Comparison to Predicate Devices

The Stomach Tube described in this 510(k) have similar technological and performance characteristics to the predicate devices. The similarities and differences between the proposed and predicate devices have been identified and explained in the comparison matrix which has been included in Section 12 of this submission. These differences have no effect on safety and effectiveness, or raise different questions of safety and effectiveness.

Similarities Between Proposed and Predicate Device

The proposed Stomach Tube and the predicate devices, All Silicone Stomach (Gastric) Tube and Pediatric Enteral Feeding Tube, have the similar intended use, principle of operation, performance characteristics and scientific technology.

Differences Between Proposed and Predicate Device

The differences between proposed and predicate devices, as shown in the following:

① **Material**

The proposed Stomach Tube is made from PVC while the predicate devices are made from PVC, silicone and PU material.

Although they are made from different materials, but the human contact components are manufactured from materials that meet all the requirements of biocompatibility, the materials in contact were tested as per ISO 10993-1. This minor differences in the tubes do not introduce new issues of safety and efficacy.

② **Size**

The proposed device is available in 6-22Fr while the predicate devices Silicone Stomach (Gastric) Tube is available in 8-18Fr and Pediatric Enteral Feeding Tube is available in 4Fr, 5Fr, 6.5Fr, 8Fr, 10Fr only. Sizes proposed (6, 20, and 22 Fr) are outside of the size range for the predicate device.

There are many FDA cleared stomach tubes which are available in various sizes. Therefore, this difference in tube diameter does not raise any new safety or effectiveness concerns as both devices are intended to be used in the same populations.

Thus, the Stomach Tube is substantially equivalent to the All Silicone Stomach (Gastric) Tube(K022112) and Pediatric Enteral Feeding Tube(K092628).

4. Summary of Non-Clinical Performance Testing

The following performance testing was conducted for the Stomach Tube:

1) General performance testing including:

- Dimensions
- Leakage
- Flow Rate Test
- Tensile Properties
- Suction Tubing Collapse Test

Testing datas and results are included in this submission, and demonstrated that the Stomach Tube meets all the pre-determined testing and acceptance criteria.

2) Biocompatibility testing as per ISO 10993-1:2009 including:

- Cytotoxicity as per ISO 10993-5:2009
- Irritation as per ISO 10993-10:2010
- Sensitization as per ISO 10993-10:2010

Biocompatibility testing reports are included in this submission, and demonstrated that the device componets that are in contact with the patient are biocompatible.

Conclusions Drawn from the Non-Clinical Testing

The results of these tests demonstrate that the device is as safe, as effective, and performs as well as the identified predicate and support a determination of substantial equivalence.

5. Conclusion

The Stomach Tube is substantially equivalent to predicate device All Silicone Stomach (Gastric) Tube (K022112). Based on the intended use, principle of operation, performance characteristics, and technological characteristics, the proposed Stomach Tube is substantially equivalent to and as safe, as effective and performs as the legally marketed predicate device.