DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 29, 2016

Well Lead Medical Co., Ltd.
c/o Huang Kaigen
Regulatory Affairs Manager
C-4 # Jinhu Industrial Estate, Hualong, Panyu
Guangzhou, 511434 CN

Re: K160801
Trade/Device Name: Well Lead Extraction Bag
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 28, 2016
Received: October 31, 2016

Dear Huang Kaigen:

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,

Jennifer R. Stevenson -A

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

510(k) Number (if known): K160801

Device Name: Well Lead Extraction Bag

Indications for Use:
The Well Lead Extraction Bag is intended for use by qualified surgeons in tissue extraction procedures during laparoscopic surgery.

Prescription Use ___X_____ OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

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

Date: 2016/10/26

Submitter: WELL LEAD MEDICAL CO., LTD.
Address:C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China

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Device Name: Well Lead Extraction Bag
Common Name: Extraction Bag, Retrieval Bag
Regulation Number: 21 CFR § 876.1500
Regulation Name: Endoscope and accessories
Product Code: GCJ
Regulatory Class: Class II

Predicate Device(s): K013872-Rüsch Memory Bag
K132375-GENICON Single-Use Specimen Retrieval Bag

1. Intended Use

The Well Lead Extraction Bag is intended for use by qualified surgeons in tissue extraction procedures during laparoscopic surgery.

2. Device Description

The Well Lead Extraction Bag is used for removal of tissue specimens during a suitable laparoscopic surgery.The device consists of a cylindrical sheath, a pusher and a polyurethane bag that minimizes spillage and intraoperative contamination by isolating and containing specimens. The bag is made of biocompatible high strength PU material, it is transparent and soft, which makes a good visuality.

The device is composed of biologically safe materials. It is supplied sterile and intended for single use only. It's easy to enter, open, close and exit, higher efficiency, and different type and size available. It is offerd in 4 types: Type A, Type B, Type C, Type D and range in bag volume from 200ml to 800ml for different surgery needs. The well thought-out rang of types and sizes are suitable for all laparoscopic procedures. The main differences between all types are the deployment system and operation method.

3. Substantial Equivalence—Comparison to Predicate Devices

※ **Similarities Between Proposed and Predicate Devices**

The proposed and predicate devices are both intended for tissue containment and removal during laparoscopic surgery. All devices are single use, sterile and offer two functional sections: a working section and a container section.

The proposed Well Lead Extraction Bag and the predicate devices, Rüsch Memory Bag, GENICON Single-Use Specimen Retrieval Bag, have the same intended use, principle of operation, patient population, performance characteristics and technological characteristics.

※ **Differences Between Proposed and Predicate Devices**

The following aspects involve slight differences between the proposed and predicate devices:

- Bag Volume
- Materials
- Deployment System
- Mechanism of the bag opening

※ **Summary and Conclusion**

The Well Lead Extraction Bag described in this 510(k) has similar technological and performance characteristics to the predicate devices. The proposed device is substantially equivalent in intended use, principle of operation, patient population, performance characteristics and technological characteristics as to predicate devices. The differences in the device do not introduce new issues of safety and efficacy, or raise different questions of safety and effectiveness.

Therefore the proposed Well Lead Extraction Bag is substantially equivalent to Rüsch Memory Bag(K013872) and GENICON Single-Use Specimen Retrieval Bag(K132375).

4. Summary of Non-Clinical Performance Testing

The following performance testing was conducted for the Well Lead Extraction Bag:

1）General performance testing including:

- Leakage
- Rated Volume
- Tensile Strength
- Determining the Dimensions

Testing datas and results are included in this submission, and demonstrated that the Well Lead Extraction Bag 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.

5. Conclusion

The Well Lead Extraction Bag is substantially equivalent to predicate devices Rüsch Memory Bag(K013872) and GENICON Single-Use Specimen Retrieval Bag(K132375). Based on the intended use, principle of operation, patient population, performance characteristics, and technological characteristics, the proposed Well Lead Extraction Bag is substantially equivalent to and as safe and as effective as the legally marketed predicate devices.