July 13, 2018

Jiangxi Yikang Medical Instrument Group Co., LTD.
Nicholas Su
Regulatory Affairs Specialist
No.188 LiduAihua Ave., Jinxian County
Nanchang, Jiangxi 331725
China

Re: K173340
Trade/Device Name: YiKang Latex Foley Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: June 8, 2018
Received: June 13, 2018

Dear Nicholas Su:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173340

Device Name
YiKang Latex Foley Catheter

Indications for Use *(Describe)*
The YiKang Latex Foley Catheter is intended to be placed in the bladder, through the urethra, to drain urine and other fluids from the urinary bladder.

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
(as requested by 21 CFR 807.92)

Submitter / 510(k) owner: Jiangxi Yikang Medical Instrument Group Co., LTD.
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Contact Person: Nicholas Su
Regulatory Affairs Specialist
E-mail: andy_smith@yeah.net

Summary Date: September 20th, 2017

Proposed Device: Device Name: YiKang Latex Foley Catheter
Common Name: Urological catheter
Classification Name: Urological catheter and accessories
Product Code: EZL
Regulation Number: 876.5130
Device Class: 2

Legally marketed predicate device to which substantial equivalence is claimed:

- Medline Latex Foley Catheter, k071423

Device Description

The YiKang Latex Foley Catheter is a flexible tubular device that is passed through the urethra into the bladder to drain urine and other fluids from the urinary bladder. The catheter is manufactured from natural latex, consists of a shaft with eyelets near the tip, balloon, drainage funnel, inflation funnel, irrigation funnel (only for 3-way) and valve. The eyelets allow for drainage of urine from the tip of the catheter through the drainage lumen. The balloon once inflated with sterile water retains the catheter within the bladder. The valve allows for inflation and deflation of the balloon.

The YiKang Latex Foley Catheter offers various balloon volumes and shaft sizes to accommodate pediatric and adult use, it is supplied in French size ranging from 6Fr to 30Fr and balloon size 3cc(ml) to 30cc(ml), the 6Fr, 8Fr and 10Fr are for pediatric use, remaining size for

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adult use. The YiKang Latex Foley Catheter consists of two types (2-way & 3-way) of devices. Two-way catheters are used for urological bladder drainage only. Three-way Foley catheters offer the option of irrigating the bladder through a 3rd lumen.

The catheter is coated with a silicone elastomer through a dipping process. The product is individually packaged with a sterile barrier pouch which is produced of plastic film plus paper through heat sealing. The product is ethylene oxide sterilized (per ISO11135), the catheter is for single use.

Indications for Use

The YiKang Latex Foley Catheter is intended to be placed in the bladder, through the urethra, to drain urine and other fluids from the urinary bladder.

Substantial Equivalence

Description	Proposed Device	Predicate Device
Name	YiKang Latex Foley Catheter	Medline Latex Foley Catheter
Intended use	The YiKang Latex Foley Catheter is intended to be placed in the bladder, through the urethra, to drain urine and other fluids from the urinary bladder.	The Medline Foley Catheter is intended to be used as a urological catheter inserted through the urethra for the purpose of drainage urine and other fluids from the urinary tract.
Patient population	Male, female and pediatric	Male, female and pediatric
Type	2-way & 3-way	2-way & 3-way
Size(Fr)	• Pediatric (6-10) • Male/Female (12-30)	• Pediatric (6-10) • Male/Female (12-30)
Balloon capacity	3cc, 5cc, 30cc	3cc, 5cc, 30cc
Operation principle	• 2-way Insert through urethra to drain urine • 3-way Insert through urethra to drain urine, meanwhile offer the option of irrigating the bladder	• 2-way Insert through urethra to drain urine • 3-way Insert through urethra to drain urine, meanwhile offer the option of irrigating the bladder
Material	Natural latex	Natural latex
Coating	Silicone	Silicone

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Labeling	Comply with 21CFR 801	Comply with 21CFR 801
Performance	Comply with ASTM F623-99	Comply with ASTM F623-99
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1
Sterility	Sterile and SAL=10^{-6}	Sterile and SAL=10^{-6}
Single use	Yes	Yes

Based on the comparison of intended use, design, material, operation principle, and performance, our YiKang Latex Foley Catheter is substantial equivalent to its predicate device which approved by FDA under k071423.

Summary of Performance testing

Performance testing have been conducted on YiKang Latex Foley Catheters per ASTM F623-99 (Reapproved 2013), and all the testing results meet requirements of ASTM F623-99 (Reapproved 2013) and defined acceptance criteria. Detailed testing conducted as follows:

- Flow Rate through Drainage Lumen
- Balloon Integrity (Resistance to Rupture)
- Inflated Balloon Response to Traction
- Balloon Volume Maintenance
- Balloon Size and Shaft Size
- Deflation Reliability (Failure to Deflate)

Biocompatibility

The YiKang Latex Foley Catheter passed biocompatibility testing of cytotoxicity, sensitization and irritation per ISO10993-1.