DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 5, 2017

Lepu Medical Technology (Beijing) Co., Ltd.
% Arthur Goddard
President
FDA Regulatory and Quality Systems Consultant
31853 Cedar Road
Mayfield Heights, Ohio 44124-4445

Re: K172099
Trade/Device Name: Shoocin™ Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 4, 2017
Received: August 9, 2017

Dear Arthur Goddard:

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 (DICE) 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 (DICE) 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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K172099

Device Name
ShoocinTM Introducer Kit

Indications for Use *(Describe)*
The ShoocinTM Introducer Kits are intended for use to facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into a vein or artery and minimize blood loss associated with such introduction.

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.

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Section 5: 510k) Summary K172099

The information on the Shoocin™ Introducer Kit is being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant: Lepu Medical Technology (Beijing) Co., Ltd.
No. 37 Chaoqian Road
Changping District, Beijing 102200
P.R. China
Telephone: +86-10-80123510
Contact: Xiangdan Kim

Date: June 30, 2017

Name: Shoocin™ Introducer Kit
Classification Name: Catheter Introducer, 870.1340
Product Code: DYB

Predicate: Shoocin™ Introducer Kit, Lepu Medical Technology (Beijing) Co., Ltd., K123475 with market clearance dates of February 3, 2014.

Modification to Predicate K123475

1. Addition of two 7Fr models to the Radial Sheath Introducer (RS070718 and RS071118).
2. Change of the radiocontrast agent in the Introducer Sheath from Bismuth to Barium sulfate (BaSO4).
3. Removal of the radiocontrast agent Bismuth in the Dilator

Description: The Shoocin™ Introducer Kit consists of a puncture needle, a guide wire with a guide wire collimator, a sheath introducer, and a dilator. The Puncture Needle incorporates a lumen, which provides a conduit for the insertion of the Guide Wire into the vascular system. The flexible stainless-steel guide wire is utilized as a guiding mechanism for the insertion of the Introducer Sheath into the vascular system. The Guide Wire contains a wire collimator, which assists in funneling the wire through the lumen of the Puncture Needle. The Guide Wire is radio-detective under fluoroscopy. The Sheath Introducer contains Barium sulfate (BaSO4), making the device visible under fluoroscopy and provides a conduit for introducing other interventional devices, including guide wires and interventional catheters, into the vascular system. The main components of this assembly are a non-hydrophilic coated Sheath Introducer, hemostasis valve housing, and a side port tubing with a 3-way stopcock/valve. The Dilator is used to provide support and stability to the Sheath Introducer during deployment into the vascular system. The proximal end of the Dilator includes a luer port and has a tapered, atraumatic distal tip. There is no radiocontrast agent on the dilator.

Indication For Use: The Shoocin™ Introducer Kits are intended for use to facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into a vein or artery and minimize blood loss associated with such introduction.

Section 5: 510k) Summary

Predicate Device Comparison: Lepu Medical Technology (Beijing) Co., Ltd. added two models to the Radial Sheath Introducer, the sheath introducer radiocontrast agent was changed from Bismuth to Barium sulfate (BaSO4), and the removal of a radiocontrast agent on the dilator to the currently marketed Shoocin™ Introducer Kit. The subject device is substantially equivalent to the predicate device in terms of intended use, indication for use, operational characteristics, and fundamental design and technology characteristics.

Biocompatibility: The Shoocin ™ Introducer Kit produced by Lepu Medical was assessed against the International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1. Guidance on selection of tests." The Shoocin ™ Introducer Kit would be classified as an External Communicating Device in contact with the Circulating Blood for a Limited Duration (<24 hours). The following test per ISO 10993 and results are:

Test	Standard	Results
Cytotoxicity	ISO 10993-5	Under the conditions of this study, the MEM test extracts would be considered no cytotoxicity potential. The negative controls, blank controls, and the positive controls performed as anticipated.
ISO Intracutaneous study	ISO 10993-10	Under the conditions of this study, the test article met the requirements of the test since the difference between each test extract overall mean score and corresponding control overall mean score was 0.0 and 0.0 for the SC and CSO test extracts, respectively.
ISO Guinea Pig Maximum Sensitization	ISO 10993-10	Under the conditions of this study, the test article extracts showed no evidence of causing delayed dermal contract sensitization in the Guinea pig. The test article was not considered a sensitizer in the Guinea pig maximization test.

Biocompatibility continue:

Test	Standard	Results
ISO Systemic Toxicity	ISO 10993-11	Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.
Complement Activation Assay	ISO 10993-4	Under the test condition, reading of C3a or Sc5b-9 of test article were significantly different ($P<0.05$) than those of negative control article.
ASTM Hemolysis	ISO 10993-4 ASTM F756	Under the conditions of this study, the Hemolytic Index for the test article in direct contact with blood was 0.9% and that for the test article extract was 0.4%. Both the test article in direct contact with blood and test article were non-hemolytic.
USP Pyrogen Study	ISO 10993-11 USP <151>	Under the conditions of this study, the maximum rise of each rabbit temperatures did not show a rise of 0.5° C or more above its baseline temperature during 3 hour observation period. The test article was judged as nonpyrogenic.
Partial Thromboplastin Time	ISO 10993-4	Under the conditions of this study, the % negative control is 68.69%, the test article would be considered mild thrombogenicity response.
In Vivo Thromboresistance	ISO 10993-4	Under the conditions of this study, the test article showed no thrombosis which was similar with the control article. The test article would be considered as thromboresistant.

Section 5: 510k) Summary

Performance Testing: The Shoocin ™ Introducer Kit modifications and new models were subjected to the following test methods (bench test) to demonstrate that these devices comply with the performance data from the predicate device.

Shoocin™ Introducer Kit Performance Testing	
Sheath Introducer	Appearance
	Size designation
	Radio-detectability
	Freedom from leakage from sheath introducer
	Freedom from leakage through haemostasis valve
	Hub
	Peak tensile force
	Dilator accessibility
3-way stopcock/ valve	Hub
Dilator	Appearance
	Size designation
	Hub
	Strength of union between hub and dilator
	Guidewire accessibility
Puncture Needle	Appearance
	Radio-detectability
	Corrosion resistance
	Size Designation
	Needle point
	Hub
	Strength of union of needle tube and needle hub
	Guidewire accessibility
Guidewire	Appearance
	Size designation
	Fracture test
	Flexing test
	Peak tensile force of guidewire
	Corrosion resistance
	Radio-detectability
Particulate evaluation	
Chemical performance	Reduced substances
	Heavy metal
	pH variation value
	Nonvolatile matter
	Residual EO and ECH
Biological	Sterile
	Bacterial endotoxin

Section 5: 510k) Summary

Sterilization: The method used is based on practices recommended by AAMI / ANSI / ISO 11135:2014 and provides a Sterility Assurance Level (SAL) of 10^{-6}.

Conclusion: The information provided in this submission and comparing intended use, principle of operation and overall technological characteristics (i.e. puncture needle, guide wire, dilator, and sheath introducer to obtain access to the vascular system), the Shoocin™ Introducer Kit supports a determination of substantially equivalent to existing legally marketed predicate device Shoocin™ Introducer Kit (K123475).