March 2, 2018

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

Re: K172331
Trade/Device Name: Brilliant Introducer Kits
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 26, 2018
Received: January 30, 2018

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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)*
K172331

Device Name
Brilliant Introducer Kit

Indications for Use *(Describe)*
The Brilliant 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.

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Section 5: 510k) Summary

K172331

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:	July, 31, 2017
Name:	Brilliant™ Introducer Kit
Classification Name:	Catheter Introducer, 870.1340
Product Code:	DYB
Predicate:	Brilliant™ Introducer Kit, Lepu Medical Technology, Ltd., K140768 with market clearance date of November 25, 2014.
Modification to Predicate K140768	1. Addition of six models to Type III (ACS061135, ACS062435, ACS070735, ACS071135, ACS071635 and ACS072435); 2. Change of the radiocontrast agent in the Sheath Introducer from Bismuth to Barium sulfate (BaSO4), and 3. Removal of the radiocontrast agent Bismuth in the Dilator; 4. Change of the coating location on the surface of Sheath Introducer, Dilator and guidewire; 5. Removal of guidewire with guidewire collimator and puncture needle in Type I, removal scalpel in Type IV.
Description:	The Brilliant™ Introducer Kit classifies into four types (Type I, II, III, and IV). Type I consists of a sheath introducer and a dilator. Type II consists of a sheath introducer, a dilator, a guide wire with a guide wire collimator and a puncture needle. Type III consists of a sheath introducer, a dilator, a guide wire with a guide wire collimator. Type IV consists of a sheath introducer, a dilator, a guide wire with a guide wire collimator, an Intravascular catheter (with needle) and a syringe. The puncture needle or an intravascular catheter incorporates a lumen, which provides a conduit for the insertion of the guide wire into the vascular system. The various types of guide wires, model dependent, are utilized as a guiding mechanism for the insertion of the introduction 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 or the intravascular catheter. The guide wire is radio-detective under fluoroscopy. The sheath introducer provides a conduit for introducing other interventional devices, including guide wires and interventional catheters, into the vasculature. The main components of the sheath introducer assembly are a hydrophilic coated sheath introducer, hemostasis valve housing, and a side port tubing with a 3-way stopcock/valve. The hydrophilic coated 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. The sheath introducer contains Barium sulfate (BaSO4), making the device visible under fluoroscopy. There is no radiocontrast agent in the dilator.

Section 5: 510k) Summary

Intended Use: The Brilliant™ 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.

Predicate Device Comparison: Lepu Medical Technology (Beijing) Co., Ltd. added six models to Type III; the sheath introducer radiocontrast agent was changed from Bismuth to Barium sulfate (BaSO4); radiocontrast agent in dilator is removed; coating location on the surface of Sheath Introducer, Dilator and guidewire is changed; guidewire with guidewire collimator and puncture needle are removed in Type I, scalpel in Type IV is remove. Compared with currently marketed Brilliant™ 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 Brilliant™ Introducer Kit produced by Lepu Medical Technology was assessed against the International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1. Guidance on selection of tests." The Brilliant ™ 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 would be required for any patient / user contacting material:

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.
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 conditions of this study, the Sc5b-9 concentration from the test article were not significantly different from that of negative control sample and Control article (P>0.05).
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 1.9% and that for the test article extract was 0.6%. 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 ℃ 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 72.32%, 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 thormboresistant.

Section 5: 510k) Summary

Performance Testing: The Brilliant™ Introducer Kit successfully passed all of the following performance tests:

Test items	
Sheath Introducer	Radio-detectability
	Peak Tensile Force between Side Port Tubing and Homeostasis Valve
Dilator	Dilator internal diameter
	Radio-detectability
	Guidewire accessibility
Coating performance	Coating integrity
	Coating efficacy
Particulate evaluation	
Residual EO and ECH	
Sterile	
Bacterial endotoxin	

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 Brilliant™ Introducer Kit supports a determination of substantial equivalence to existing legally marketed predicate device Brilliant ™ Introducer Kit (K140768).