December 17, 2018

Boston Scientific Corporation
Jia Huang
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K172520
Trade/Device Name: CRE™ RX Biliary Balloon Dilatation Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: August 18, 2017
Received: August 21, 2017

Dear Jia Huang:

This letter corrects our substantially equivalent letter of October 4, 2017.

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,

Charles Viviano -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)*
K172520

Device Name
CRE™ RX Biliary Balloon Dilatation Catheter

Indications for Use *(Describe)*
CRE™ RX Biliary Balloon Dilatation Catheter is indicated for use in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy. The CRE™ RX Biliary Balloon Dilatation Catheters may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.

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

1. Submitter:

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Contact: Jia Huang
Senior Specialist, Regulatory Affairs
Date Prepared: August 17, 2017

2. Proposed Device:

Trade Name: CRE™ RX Biliary Balloon Dilatation Catheter
Classification Name: Biliary Catheter and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

3. Predicate Device:

Trade Name: CRE™ PRO Wireguided Balloon Dilatation Balloon
510(k) Number: K112994
Classification Name: Biliary Catheter and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

Trade Name: Hurricane™ RX Biliary Balloon Dilatation Catheter
510(k) Number: K130484
Classification Name: Biliary Catheter and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

Reference Device:

Trade Name: CRE™ Pulmonary Balloon Dilatation Catheter
510(k) Number: K170759
Classification Name: Bronchoscope (flexible or rigid) and Accessories
Regulation Number: 874.4680
Product Code: KTI
Classification: Class II

4. Proposed Device Description:

The CRE™ RX Biliary Balloon Dilatation Catheter is capable of inflating balloon to 3 distinct and progressively larger size diameters via controlled radial expansion. The specific balloon sizes are printed on each package and flag label.

The CRE™ RX Biliary Balloon Dilatation Catheter is designed to pass through a 3.7 mm or greater working channel of a duodenoscope and accept a 0.035 in (0.89 mm) guidewire through its guidewire lumen.

The CRE™ RX Biliary Balloon Dilatation Catheter has three lumens: balloon inflation lumen, guidewire lumen and contrast injection lumen. A FloSwitch™ Adapter is connected to the hub of the "Injection" lumen. The FloSwitch Adapter is to remain closed until distal contrast medium injections are required.

5. Indications for Use:

CRE™ RX Biliary Balloon Dilatation Catheter is indicated for use in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy. The CRE™ RX Biliary Balloon Dilatation Catheters may be used for injection of contrast medium for fluoroscopic visualization of the bile ducts.

The indications for use are similar when compared to those of the predicates CRE™ PRO Wireguided Balloon Dilatation Catheter (K112994) and Hurricane™ RX Biliary Balloon Dilatation Catheter (K130484).

6. Technological Characteristics:

The proposed CRE™ RX Biliary Balloon Dilatation Catheter has identical intended use as the predicates CRE™ PRO Wireguided Balloon Dilatation Catheter (K112994) and Hurricane™ RX Biliary Balloon Dilatation Catheter (K130484). The proposed CRE™ RX Biliary Balloon Dilatation Catheter has similar technological characteristics as the predicates CRE™ PRO Wireguided Balloon Dilatation Catheter (K112994) and Hurricane™ RX Biliary Balloon Dilatation Catheter (K130484) and reference CRE™ Pulmonary Balloon Dilatation Catheter (K170759).

Although the technological characteristics of the CRE™ RX Biliary Balloon Dilatation Catheter are not completely identical to either of the predicate devices, the technological characteristics of the proposed CRE™ RX Biliary Balloon Dilatation Catheter are the combination of the technological characteristics of the two predicates and can fulfil the identical intended use as that of the two predicate devices.

The proposed CRE™ RX Biliary Balloon Dilatation Catheter has the same design as predicate CRE™ PRO Wireguided Balloon Dilatation Catheter (K112994) and reference CRE™ Pulmonary Balloon Dilatation Catheter (K170759) in terms of balloon controlled radial expansion that the balloon will dilate to three distinct and progressively larger size diameters at or above 3 atm (304 kPa).

The proposed CRE™ RX Biliary Balloon Dilatation Catheter has the same design as predicate Hurricane™ RX Biliary Balloon Dilatation Catheter (K130484) in terms of guidewire rapid exchange and contrast medium injection that the guidewire can exit the proposed CRE™ RX Biliary Balloon Dilatation Catheter at the guidewire exit port in order to be locked in place and the distal bile duct can be viewed fluoroscopically by contrast medium injection through the injection lumen of the proposed CRE™ RX Biliary Balloon Dilatation Catheter.

The proposed CRE™ RX Biliary Balloon Dilatation Catheter has the identical 3 cm length balloon as the 3 cm balloon of the reference CRE™ Pulmonary Balloon Dilatation Catheter (K170759) that will provide physician another length option to dilate the Sphincter of Oddi using the proposed CRE™ RX Biliary Balloon Dilatation Catheter.

The proposed CRE™ RX Biliary Balloon Dilatation Catheter has similar material as predicates CRE™ PRO Wireguided Balloon Dilatation Catheter (K112994) and Hurricane™ RX Biliary Balloon Dilatation Catheter (K130484) and reference CRE™ Pulmonary Balloon Dilatation Catheter (K170759).

7. Performance Data:

The proposed CRE™ RX Biliary Balloon Dilatation Catheter meets the requirements of ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing", ISO 11135-1 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices" and ISO 10993-7 "Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals".

The following bench tests were performed on the proposed CRE™ RX Biliary Balloon Dilatation Catheter: Inflate, Deflate, Shaft Kink Resistance, Scope Insertion, Scope Removal, Shaft Tensile, Tunnel Tensile, Lumen Mandrel Removal, Contrast Injection, Hub Luer Lock Fittings.

The testing performed demonstrated that the proposed device is substantially equivalent to the predicate devices because the acceptance criteria of these product specifications are identical or similar to those of the predicate devices.

8. Conclusion:

All biocompatibility tests conducted on the proposed CRE™ RX Biliary Balloon Dilatation Catheter passed. Therefore, the proposed device is considered biocompatible for its intended use.

All device bench test results were acceptable. The data demonstrate that the proposed CRE™ RX Biliary Balloon Dilatation Catheter sufficiently meets the design specifications and is suitable for the intended use.

Boston Scientific Corporation has demonstrated that the proposed CRE™ RX Biliary Balloon Dilatation Catheter is substantially equivalent to the currently marketed CRE™ PRO Wireguided Balloon Dilatation Catheter (K112994) and Hurricane™ RX Biliary Balloon Dilatation Catheter (K130484) and can be safely and effectively used for its proposed indications.