DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2017

Creganna Medical
Orla Hickey
Regulatory Affairs
Parkmore West
Galway, Ireland

Re: K162253
Trade/Device Name: Trapper™ Exchange Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 23, 2016
Received: November 30, 2016

Dear Orla Hickey:

This letter corrects our substantially equivalent letter of January 6, 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 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" (21CFR 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,

Michael John -S 2017.03.07 15:25:37 -05'00'

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)*
K162253

Device Name
Trapper™ Exchange Device

Indications for Use *(Describe)*
Trapper Exchange Device is indicated to facilitate interventional device exchange while maintaining wire position in patients undergoing PCI procedures. Trapper Exchange Device is not intended for use outside of the guide catheter.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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510(k) Summary

General Information

Date:	16 January 2017
Classification:	Class II, 21 CFR 870.1250, Percutaneous Catheter
Product Code:	DQY
Trade Name:	Trapper™ Exchange Device
Common Name:	Percutaneous Catheter
Model Numbers:	SA4103-01
Submitter:	Creganna Medical, Parkmore West, Galway, Ireland
Regulatory Contact:	Orla Connaughton Regulatory Affairs Director Creganna Medical Parkmore West Galway, Ireland Tel: + 91 783469 Email: CREG-GALRegulatory@te.com

Intended Use

Trapper Exchange Device is indicated to facilitate interventional device exchange while maintaining wire position in patients undergoing PCI procedures. Trapper Exchange Device is not intended for use outside of the guide catheter.

Predicate Devices

- Boston Scientific Legacy Trapper Device, P860019 S040 (Primary Predicate)
- Boston Scientific Emerge PTCA Catheter, K113220

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Device Description

Boston Scientific Trapper™ Exchange Device is an accessory device used to facilitate interventional device exchange while maintaining wire position in patients undergoing Percutaneous Coronary Intervention (PCI) procedures. Trapper™ Exchange Device is a fixed wire catheter that has a balloon near the distal tip. The 10mm balloon is designed to secure a 0.014inch wire within a 6F to 8F guide catheter when inflated to 12atm. There is a 1mm radiopaque marker band in the tip and a 2mm marker band at the proximal edge of the balloon to facilitate its placement and identification during catheter exchanges. Trapper™ Exchange Device has a single lumen luer hub for inflation and deflation of the balloon. The proximal shaft has markings with an adjustable stop for 90cm and 100cm guide catheter lengths to facilitate balloon placement. The proximal stop is pre-set for a 90cm guide.

Trapper™ Exchange Device is designed for use with guide catheters having internal lumen diameters in the range of 6F (0.070inch or 1.7mm) to 8F (0.091inch or 2.3mm) and lengths ≥ 90cm. In 6F guide catheters the PCI catheter to be exchanged must have a shaft OD (Outer Diameter) ≤ 3.2F (0.043inch or 1.1mm).

The set is supplied as a single use sterile device.

Materials

The Boston Scientific Trapper™ Exchange Device is comprised of materials that are commonly used in medical device applications, including implantable medical devices. The biological safety tests performed in accordance with ISO 10993-1 (Biological evaluation of medical devices -- Part 1: Evaluation and testing) for external communicating devices, circulating blood, limited duration demonstrate that the device is biocompatible for its intended use.

The tests performed to demonstrate the biocompatibility of the device were:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity/Irritation
- Acute Systemic Toxicity
- Hemocompatibility
- Thromboresistance
- Material Mediated Pyrogenicity

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Comparison of Technological Characteristics of Trapper™ Exchange Device compared to the Predicate Device

The Trapper™ Exchange Device and the equivalent commercialized predicate device Boston Scientific Emerge PTCA Catheter and the legacy Boston Scientific Trapper™ Exchange Device were evaluated for substantial equivalence. No significant difference in clinical, technical and biological parameters was identified between the Trapper™ Exchange Device and thepredicate devices. All three of the devices have the same clinical principal of operation; all inflate a balloon with a constrained diameter in order to achieve their intended use during PCI procedures in the same patient population. Both Trapper™ devices are (were) intended to hold a guidewire in place within the guide catheter and Emerge is intended for the treatment of coronary lesions within the vasculature. In general, all of these devices are used in interventional coronary procedures. These devices have similar designs and the materials that are used meet the same biological standards. Based on this and the design and engineering data provided, the Trapper™ Exchange Device has been shown to be substantially equivalent to the commercialized Emerge PTCA Catheter and the legacy Boston Scientific Trapper™ Exchange Device.

Non Clinical Information

The determination of substantial equivalence is also based on an assessment of non-clinical engineering tests, as listed in **Table 1-1, Table 1-2** and **Table 1-3.**

Design Verification Tests	
Device Surface	Kink Radius
Proximal Positioning Aid	Withdrawal into a Guide (Challenge)
Effective Length	Proximal Markers (Telescope)
Balloon Alignment	Catheter Exchange force
Dye Flow Rate	Packaging Integrity
Trap Force	Sterile Barrier Integrity, Visual
Balloon Outer Diameter	Packaging Seal Strength
Rated Burst Pressure (RBP)	Packaging and Labelling Configuration
Burst Mode	Shelf Carton Condition
Deflation Time	Label Adhesion and Print Quality
Tip Design	Package Labelling Elements & Appearance
Repeat Inflation	Instructions for Use
Repeat Delivery & Use (Challenge)	Manifold Orientation in Header Bag
Full Unit Tensile (including tip)	Removal of Product From Packaging
Stretch Robustness (challenge)	

Table 1-1: List of Design Verification Tests

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Design Validation Tests	
Shelf Carton Condition	Catheter Exchange Force
Packaging Integrity	Marker band Visibility
Removal of Product from Packaging	Trap Force
Interface with Ancillary Devices	Deflation Time
Telescope Movement Force	Burst Mode

Table 1-2: List of Design Validation Tests (Bench)

Design Validation Tests	
Trap Force	Marker band Visibility
Catheter Exchange Force	

Table 1-3: List of Design Validation Tests (Physician)

The Bench Testing Summary Reports are located in **Attachment 9** and the Biocompatibility Reports are located in **Attachment 8.**

The test results demonstrate that the Trapper™ Exchange Device meets the requirements in the applicable standards and specifications, and is substantially equivalent to legally marketed predicate device.

Clinical Information

Clinical studies were not deemed necessary for the Trapper™ Exchange Device since bench testing and a clinical literature review were sufficient to demonstrate substantial equivalence by way of comparison to a legally marketed predicate device and a previously legally marketed predicate device.

Summary of Substantial Equivalence

Creganna Medical believes the Trapper™ Exchange Device is substantially equivalent to the predicate devices based on the nonclinical and clinical literature review as discussed above. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to an existing legally marketed predicate product (Emerge PTCA Catheter) and a product that was legally marketed from 1996-2005 (Legacy Trapper™ Exchange Device).