



November 4, 2016

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

Boston Scientific Corporation
Ka Xiong
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K162350

Trade/Device Name: Coyote Monorail Percutaneous Transluminal Angioplasty Balloon
Dilatation Catheter,
Sterling Monorail Percutaneous Transluminal Angioplasty Balloon
Dilatation Catheter,
Sterling Monorail Percutaneous Transluminal Angioplasty Balloon
Dilatation Catheter,
Sterling SL Monorail Percutaneous Transluminal Angioplasty
Balloon Dilatation Catheter,
Ultra-Soft SV Monorail Balloon Dilatation Catheter 0.018"

Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: October 6, 2016
Received: October 7, 2016

Dear Ka Xiong:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices 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 devices 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 devices 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" (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 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162350

Device Name

Coyote™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter

Indications for Use (Describe)

The Coyote MONORAIL PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Indications for Use

510(k) Number (if known)

K162350

Device Name

Sterling™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter

Indications for Use (Describe)

The Sterling Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

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)

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Indications for Use

510(k) Number (if known)

K162350

Device Name

Sterling™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter

Indications for Use (Describe)

The Sterling Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

K162350

Device Name

Sterling™ SL Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter

Indications for Use (Describe)

The Sterling SL Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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)

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Indications for Use

510(k) Number (if known)

K162350

Device Name

Ultra-Soft SV™ Monorail™ Balloon Dilatation Catheter 0.018"

Indications for Use (Describe)

The Ultra-soft SV Balloon Dilatation Catheter is recommended for the Percutaneous Transluminal Angioplasty of the iliac, femoral, ilio-femoral, popliteal, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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)

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K162350

510(k) Summary

Per 21 CFR §807.92

Common or Usual Name	Percutaneous Transluminal Angioplasty Dilatation Catheter	
Trade Name(s)	Coyote™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter – formally known as .014 Monorail PTA Dilatation Catheter	
Product Code	LIT - Catheter, Angioplasty, Peripheral, Transluminal	
Classification of Device	Class II - 21 CFR 870.1250	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Ka Zoua Xiong Regulatory Affairs Specialist Phone: 763-494-2970 Fax: 763-494-2222 Email: Kazoua.Xiong@bsci.com	
Date Prepared	06 October 2016	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	Owner /Operator:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 9912058
	Manufacturing Facility:	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	Sterilization Facilities:	BSC Coventry 8 Industrial Drive Coventry, RI 02816 USA
Predicate Devices	K111295 - Coyote™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter, cleared 31 May 2011	

Device Description	The Coyote™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheters (Coyote MR) are high performance balloon catheters for peripheral vascular indications. The devices feature an ultra low profile, semi-compliant balloon combined with a low profile tip. The catheter is compatible with 0.014 in (0.36 mm) guidewires.
Intended Use/ Indications for Use	The Coyote MONORAIL PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Comparison of Required Technological Characteristics	The proposed Coyote MR is substantially equivalent to the existing Coyote MR cleared by FDA under premarket notification K111295 (31May2011). Coyote MR has the same intended use, scientific technology, design (with the exception of the corewire design), materials, sterilization method, and packaging materials as the applicable predicate device.
Summary of Non-Clinical Test Summary	Bench and first article testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device with the modified corewire has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Coyote MR with the modified corewire has been shown to be appropriate for its intended use and is considered to be substantially equivalent to its predicate (K111295).

K162350

510(k) Summary

Per 21 CFR §807.92

Common or Usual Name	PTA Balloon Dilatation Catheter	
Trade Name(s)	Sterling™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter	
Product Code	DQY - Catheter, Percutaneous	
Classification of Device	Class II - 21 CFR 870.1250	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Ka Zoua Xiong Regulatory Affairs Specialist Phone: 763-494-2970 Fax: 763-494-2222 Email: Kazoua.Xiong@bsci.com	
Date Prepared	06 October 2016	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	Owner /Operator:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 9912058
	Manufacturing Facility:	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	Sterilization Facilities:	BSC Coventry 8 Industrial Drive Coventry, RI 02816 USA Synergy Health (Tullamore) IDA Business & Technology Park Tullamore County Offaly Ireland

Predicate Devices	<p>K053118 - Sterling™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter, cleared 16 December 2005</p> <p>K141150 - Sterling™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter, cleared 25 September 2014</p>
Device Description	<p>The Sterling™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter (Sterling MR) is a Monorail brand rapid exchange catheter with a semi-compliant balloon fixed at the distal tip. The balloon catheter has a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guidewires 0.014 in / 0.018 in (.36 mm / .46 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures</p>
Intended Use/ Indications for Use	<p>The Sterling Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.</p>
Comparison of Required Technological Characteristics	<p>The proposed Sterling MR is substantially equivalent to the existing Sterling MR devices cleared by FDA under premarket notifications K053118 (16Dec2005) and K141150 (25Sep2014). Sterling MR has the same intended use, scientific technology, design (with the exception of the corewire design), materials, sterilization method, and packaging materials as the applicable predicate device.</p>
Summary of Non-Clinical Test Summary	<p>Bench testing and first article testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device with the modified corewire has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.</p>
Conclusion	<p>Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Sterling MR with the modified corewire has been shown to be appropriate for its intended use and is considered to be substantially equivalent to its predicate (K053118).</p>

K162350

510(k) Summary

Per 21 CFR §807.92

Common or Usual Name	PTA Balloon Dilatation Catheter	
Trade Name(s)	Sterling™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter	
Product Code	LIT - Catheter, Angioplasty, Peripheral, Transluminal	
Classification of Device	Class II - 21 CFR 870.1250	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Ka Zoua Xiong Regulatory Affairs Specialist Phone: 763-494-2970 Fax: 763-494-2222 Email: Kazoua.Xiong@bsci.com	
Date Prepared	06 October 2016	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	Owner /Operator:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 9912058
	Manufacturing Facility:	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	Sterilization Facilities:	BSC Coventry 8 Industrial Drive Coventry, RI 02816 USA Synergy Health (Tullamore) IDA Business & Technology Park Tullamore County Offaly Ireland

Predicate Devices	K141150 - Sterling™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter, cleared 25 September 2014
Device Description	The Sterling™ Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter (Sterling MR) is a Monorail brand rapid exchange catheter with a semi-compliant balloon fixed at the distal tip. The balloon catheter has a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guidewires 0.014 in / 0.018 in (.36 mm / .46 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures.
Intended Use/ Indications for Use	The Sterling Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.
Comparison of Required Technological Characteristics	The proposed Sterling ME is substantially equivalent to the existing Sterling ME cleared by FDA under premarket notification K141150 (25Sep2014). Sterling ME has the same intended use, scientific technology, design (with the exception of the corewire design), materials, sterilization method, and packaging materials as the applicable predicate device.
Summary of Non-Clinical Test Summary	Bench testing and first article testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device with the modified corewire has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Sterling ME with the modified corewire has been shown to be appropriate for its intended use and is considered to be substantially equivalent to its predicate (K141150).

K162350

510(k) Summary

Per 21 CFR §807.92

Common or Usual Name	Percutaneous Transluminal Angioplasty Dilatation Catheter	
Trade Name(s)	Sterling™ SL Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter	
Product Code	LIT - Catheter, Angioplasty, Peripheral, Transluminal	
Classification of Device	Class II - 21 CFR 870.1250	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Ka Zoua Xiong Regulatory Affairs Specialist Phone: 763-494-2970 Fax: 763-494-2222 Email: Kazoua.Xiong@bsci.com	
Date Prepared	06 October 2016	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	Owner /Operator:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 9912058
	Manufacturing Facility:	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	Sterilization Facilities:	BSC Coventry 8 Industrial Drive Coventry, RI 02816 USA Synergy Health (Tullamore) IDA Business & Technology Park Tullamore County Offaly Ireland
Predicate Devices	K093720- Sterling™ SL Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter, cleared 23 December 2009	

Device Description	<p>The Sterling™ SL Monorail™ Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter (Sterling SL) is high performance balloon catheter for peripheral vascular indications featuring a low profile, semi-compliant balloon combined with a low profile tip. They are a line extension to the existing Sterling catheters and include smaller diameter and longer length balloons. The catheters have a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guidewires 0.014" (0.36 mm) or 0.018" (0.46 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated.</p>
Intended Use/ Indications for Use	<p>The Sterling SL Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.</p>
Comparison of Required Technological Characteristics	<p>The proposed Sterling SL is substantially equivalent to the existing Sterling SL cleared by FDA under premarket notification K093720 (23Dec2009). Sterling SL has the same intended use, scientific technology, design (with the exception of the corewire design), materials, sterilization method, and packaging materials as the applicable predicate device.</p>
Summary of Non-Clinical Test Summary	<p>Bench testing and first article testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device with the modified corewire has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.</p>
Conclusion	<p>Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Sterling SL with the modified corewire has been shown to be appropriate for its intended use and is considered to be substantially equivalent to its predicate (K093720).</p>

K162350

510(k) Summary
Per 21 CFR §807.92

Common or Usual Name	Balloon Dilation Catheter	
Trade Name(s)	Ultra-Soft SV™ Monorail™ Balloon Dilatation Catheter 0.018"	
Product Code	DQY - Catheter, Percutaneous	
Classification of Device	Class II - 21 CFR 870.1250	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Ka Zoua Xiong Regulatory Affairs Specialist Phone: 763-494-2970 Fax: 763-494-2222 Email: Kazoua.Xiong@bsci.com	
Date Prepared	06 October 2016	
Section 514 of the Act Performance Standards	Currently no FDA mandated or voluntary performance standards exist for this device.	
Establishment Registration Numbers	Owner /Operator:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 9912058
	Manufacturing Facility:	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	Sterilization Facilities:	BSC Coventry 8 Industrial Drive Coventry, RI 02816 USA
Predicate Devices	K021735- Ultra-Soft SV™ Monorail™ Balloon Dilatation Catheter 0.018", cleared 08 August 2002	

Device Description	The Ultra-Soft SV™ Monorail™ Balloon Dilatation Catheter 0.018 is a sterile, single use, Monorail catheter with a semi-compliant balloon near the distal tip which inflates to a known diameter and length at a specific pressure. The catheter consists of a double lumen at the distal end and a single lumen catheter at the proximal end. The 0.018 in. guide wire compatible balloon catheter is available in diameters of 4.0 - 7.0 mm in 1.5 and 2.0 cm balloon lengths.
Intended Use/ Indications for Use	The Ultra-soft SV Balloon Dilatation Catheter is recommended for the Percutaneous Transluminal Angioplasty of the iliac, femoral, ilio-femoral, popliteal, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Comparison of Required Technological Characteristics	The proposed USSV MR is substantially equivalent to the existing USSV MR cleared by FDA under premarket notification K021735 (08Aug2002). USSV MR has the same intended use, scientific technology, design (with the exception of the corewire design), materials, sterilization method, and packaging materials as the applicable predicate device.
Summary of Non-Clinical Test Summary	Bench testing and first article testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device with the modified corewire has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed USSV MR with the modified corewire has been shown to be appropriate for its intended use and is considered to be substantially equivalent to its predicate (K021735).