September 16, 2020

Scientia Cardio Access LLC
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k, Saint Paul, Minnesota 55114

Re: K193194
Trade/Device Name: CrossTorq 14 Guidewire
Regulation Number: 21 CFR 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX

Dear Prithul Bom:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 13, 2019. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lydia Glaw, OHT2: Office of Cardiovascular Devices, 301-796-1456, Lydia.glaw@fda.hhs.gov.

Sincerely,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2020.09.16 10:45:14 -04'00'

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Interventional Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

December 13, 2019

Scientia Cardio Access LLC
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k, Saint Paul, Minnesota 55114

Re: K193194
Trade/Device Name: CrossTorq 14 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 18, 2019
Received: November 19, 2019

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2019.12.13 09:46:48 -05'00'

Lydia Glaw, Ph.D.
Assistant Director
DHT2C: Division of Coronary
and Peripheral Interventional Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K193194

Device Name
CrossTorq 14 Guidewire

Indications for Use *(Describe)*
The CrossTorqTM 14 Guidewire is intended for general vascular use within the coronary and peripheral vasculatures to introduce and position catheters and other interventional devices. The CrossTorqTM 14 Guidewire is not intended for use in the neurovasculature.

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.

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510(K) SUMMARY

(Per 21 CFR 807.92)

SCIENTIA CARDIO ACCESS LLC
CrossTorq™ 14 Guidewire

510(k) Sponsor: Scientia Cardio Access LLC
3487 West 2100 South Suite 100
West Valley City, UT 84119
Tel: (775) 657-6330

Contact Person: Amy McManus, Regulatory Affairs Manager
Phone: 1 (888) 385-9016
Email: amcmanus@scientiavascular.com

Date Prepared: December 6, 2019

Prepared by: Ryan O'Callaghan, MS, RAC
Phil Triolo and Associates LC
Tel: 801.573.2651
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Trade Name:	CrossTorq™ 14 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Product Code:	DQX
Predicate Devices:	Kinetix™ Guidewire (K081021) Hornet™ Guidewire, Hornet™ 10 Guidewire, and Hornet™ 14 Guidewire (K152231)
Reference Devices:	Aristotle 14 Guidewire (K173235) Aristotle 18 Guidewire (K183608)

DEVICE DESCRIPTION

Scientia Cardio Access's CrossTorq™ 14 Guidewire is a 0.014" diameter steerable guidewire with a shapeable tip to aid in accessing vasculature. The guidewire is supplied sterile and is for single use only. It is provided with the 4 different tip loads, or tip stiffnesses; 1 gram, 6 gram, 10 gram, and 15 gram. These tip stiffnesses are referred to as Soft, Standard, Support, and Extra Support, respectively. The product is offered in lengths of 200cm and 300cm.

The distal portion of the guidewire tip includes a radiopaque platinum wire marker coil to facilitate fluoroscopic visualization. The guidewire has a hydrophilic polymer coating on the distal portion and a polytetrafluoroethylene (PTFE) coating on the proximal portion to reduce friction during manipulation in vessels.

The guidewire is provided with a shaping mandrel (to shape the flexible tip of the guidewire), an introducer (to aid with the insertion of the guidewire into a catheter hub and/or a hemostasis valve) and a torque device (to attach to the proximal portion to facilitate gripping and manipulation of the guidewire during use). The shaping mandrel, introducer and torque accessory devices are included to facilitate use of the guidewire and are not intended to contact the patient's body.

The CrossTorq 14 Guidewire is substantially equivalent with respect to technological characteristics, design and materials to Boston Scientific's currently marketed Kinetix™ Guidewire cleared under K081021 and Boston Scientific's Hornet™ Guidewire, Hornet™ 10 Guidewire, and Hornet™ 14 Guidewire (also referred to as the Hornet Guidewire Series in this summary) cleared under K152231.

INDICATIONS FOR USE

The CrossTorq™ 14 Guidewire is intended for general vascular use within the coronary and peripheral vasculatures to introduce and position catheters and other interventional devices. The CrossTorq™ 14 Guidewire is not intended for use in the neurovasculature.

TECHNOLOGICAL CHARACTERISTICS

As shown in the table below, the technological characteristics of the CrossTorq 14 Guidewire are equivalent to those of the predicate devices, the Kinetix Guidewire and Boston Scientific Hornet Guidewire Series. Both of the predicate devices have the same intended use; however, the Kinetix Guidewire is only offered in soft tip stiffness profiles, while the Hornet Guidewire Series and the CrossTorq 14 Guidewire are offered in a wider range of stiffness profiles. The CrossTorq 14 Guidewire combines the stiffness profiles offered by the Kinetix and Hornet Guidewire Series guidewires.

Comparison of Technological Characteristics between Subject Device and Predicate Devices				
Characteristic	**Subject Device CrossTorq™ 14 Guidewire**	**Primary Predicate Device Kinetix™ Guidewire (K081021)**	**Predicate Device Boston Scientific Hornet Guidewire Series (K152231)**	**Comparison**
Anatomical Location	Coronary and peripheral vasculature	Coronary and peripheral vasculature	Coronary and peripheral vasculature	Same
Dimensions	***O.D.:*** 0.014" (0.36mm) ***Length:*** 200cm or 300cm	***O.D.:*** 0.014" (0.36mm) ***Length:*** 180cm or 300cm	***O.D.:*** 0.014" (0.36mm) ***Length:*** 190cm or 300cm	Equivalent
Core Wire	Stainless Steel	Nitinol	Stainless Steel	Equivalent
Distal Tip	Shapeable straight tip ***Length:*** 35 cm ***Material****:* Nitinol	Shapeable straight tip or preshaped "J" tip ***Length:*** 18 cm ***Material:*** Nitinol	Shapeable straight tip ***Length:*** 15 cm ***Material****:* Stainless Steel	Equivalent
Stiffness Profiles	Range from Soft(1gram) to Extra Support (15gram)	Range from Moderate Support(0.8 gram) to Plus(1.3gram)	Range from 1gram to 14 gram tip stiffness	Equivalent
Coatings	***Distal End:*** Hydrophilic ***Proximal End:*** PTFE	***Distal End:*** Hydrophilic ***Proximal End:*** PTFE	***Distal End:*** Hydrophilic ***Proximal End:*** PTFE	Same
Radiopaque Marker	Radiopaque marker at distal tip	Radiopaque marker at distal tip	Radiopaque marker at distal tip	Same
Accessories	The following accessories are provided with the guidewire: • Shaping Mandrel • Torque Device • Plastic Introducer	No accessories are provided with the predicate device. The predicate device's IFU references use of the guidewire with the following accessories: • Shaping instrument • Torque device • Insertion tool	No accessories are provided with the predicate device. The predicate device's IFU references use of the guidewire with the following accessories: • Shaping instrument • Torque device • Insertion tool	Equivalent

Comparison of Technological Characteristics between Subject Device and Predicate Devices				
Characteristic	**Subject Device CrossTorq™ 14 Guidewire**	**Primary Predicate Device Kinetix™ Guidewire (K081021)**	**Predicate Device Boston Scientific Hornet Guidewire Series (K152231)**	**Comparison**
Sterilization Method	100% Ethylene Oxide (EO)	100% Ethylene Oxide (EO)	100% Ethylene Oxide (EO)	Same

As shown in the Table above, the CrossTorq 14 Guidewire differs from the predicate guidewire in the following ways:

The CrossTorq 14 core wire is constructed of stainless steel, while the Kinetix core wire is constructed of Nitinol. The Hornet Guidewire Series guidewires are all built using the same stainless steel material as the CrossTorq 14. Stainless steel is a commonly used core wire material and the functionality and performance characteristics of the stainless steel core wire are similar to those of the Nitinol core wire used in the construction of the Kinetix Guidewire.

An accessory kit (consisting of a shaping mandrel, a torque device, and an introducer) is provided as part of the subject device, whereas the predicate devices do not provide an accessory kit as part of their finished product. Although the accessories are not provided in the packaging, the Kinetix and Hornet Guidewire Instructions For Use mentions the use of a shaping instrument, insertion tool, and torque device, which are equivalent to the accessories provided with the CrossTorq 14.

The tip stiffness profiles available for the CrossTorq 14 Guidewire are: 1gram, 6 gram, 10 gram, and 15 gram. These tip stiffnesses are referred to in reports and this document as Soft, Standard, Support, and Extra Support, respectively. The predicate Kinetix Guidewire is only available in 0.8 gram and 1.3 gram tips, however, the predicate Hornet Guidewire series is available in 1 gram, 10 gram, and 14 gram tips, and thus can be used to determine values for comparative testing of Tip Stiffness and Column Buckling.

Results of tests performed on the new CrossTorq 14 Guidewire demonstrate that the new guidewire performs as well as the predicate devices and/or meets requirements of relevant standards. Further, any differences in technological characteristics of the CrossTorq 14 Guidewires when compared with predicate device characteristics do not raise different questions of safety and effectiveness.

Additionally, the indications for use statement of the subject device is equivalent to that of the predicate devices and the differences in wording are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device. The differences do not affect the safety and effectiveness of the device when used as labeled, as the same intent is documented for the predicate devices and the new device.

NON-CLINICAL PERFORMANCE TESTS

Biocompatibility

The materials and processing of the CrossTorq 14 Guidewires are identical to those of the reference Aristotle 18 Guidewire (manufactured by Scientia Cardio Access LLC's sister company, Scientia Vascular LLC, and cleared under K183608); in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) with the exception that the outer diameter of the CrossTorq 14 Guidewire is smaller than that of the Aristotle 18 Guidewire. The dimensional change does not alter the chemical or physical properties of the medical device in its final finished form, and therefore, results from the Aristotle 18 Guidewire can be applied to the medical device in its final finished form.

There are no additional biologic interactions that need to be considered in order to use the cleared guidewires in the coronary vasculature. Consequently, no additional evaluations are needed to determine that the subject guidewires present a low and acceptable biological and toxicological risk when used in accordance with their intended and indicated uses, and no additional biological safety information is provided in this 510(k).

Test Results Leveraged from Premarket Notifications K173235 (Aristotle 14 Guidewire) and K183608 (Aristotle 18 Guidewire)

Results for following tests, performed on the reference Aristotle 14 Guidewires and reference Aristotle 18 Guidewires, were included in Scientia Vascular LLC's premarket notifications K173235 and K183608 for the Aristotle 14 Guidewire and Aristotle 18 Guidewire, respectively. The results from these tests are also applicable to CrossTorq 14 Guidewire, as the materials and processing of the CrossTorq 14 Guidewires are identical to those of the Aristotle 14 and Aristotle 18 Guidewires.

Summaries of Leveraged Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Radiopacity	Guidewires evaluated by physicians in human cadaver	Guidewires exhibited acceptable radiopacity.
Corrosion Resistance	Test for corrosion resistance per ISO 11070	There were no signs of corrosion on guidewires after soaking in typical end-use solutions.
Chemical Compatibility	Guidewires were exposed to saline and contrast agent/saline solutions and examined for degradation.	All guidewires showed no signs of degradation, corrosion or physical decomposition after exposure.
Latex	Tested for trace latex proteins per ASTM D6499-07	No detectable traces of latex were found.
Accessories Testing	Compatibility of Torque Device and Shaping Mandrel with Aristotle Guidewires was evaluated in cadaver testing and simulated use evaluations. Various tests on Shaping Mandrel per ISO 11070: biocompatibility, visual inspection, corrosion resistance, tensile testing, luer taper dimensions	Acceptance criteria of all tests were met
Package Integrity	Simulated transportation test per ASTM D 4169:16. Pouch evaluated for seal strength per ASTM F 88-15 and leak tests (bubble test) per ASTM F 2096-11	Following exposure to typical storage and transportation conditions, all sterile barrier pouches maintained their integrity and labeling remained affixed and legible.

Summaries of Leveraged Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Sterilization Validation	100% EO is used to sterilize the device to achieve a SAL of at least 10^{-6}. The device was adopted into an EO sterilization processing group in accordance with AAMI TIR 28:2009. Validation of the EO sterilization cycle was performed using the Half-cycle, overkill approach described in Section B.1.2 of ISO11135:2007 Annex B.	Results justified adoption into the EO sterilization processing group: Comparative and Bioburden Resistance study results demonstrated that PCDs are more difficult to sterilize than devices; Bioburden Enumeration and Extraction Efficiency tests were used to enumerate the CFUs present on devices; and Bacteriostasis/ Fungistasis test results demonstrated that the product does not inhibit the growth of organisms.
Sterilization Validation: EO and ECH Residuals	Measured EO and ECH residuals per AAMI/ANSI/ISO 10993-7	The residual traces of EO and ECH remaining in the CrossTorq 14 Guidewire after exposure to the EO sterilization process are well below the limits specified in ISO 10993-7.
Sterilization Validation: Bacterial Endotoxin Levels	LAL testing was conducted in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, and USP <85>, using the kinetic chromogenic method.	< 2.15 EU/device

Functional Testing performed on CrossTorq 14 Guidewires

Functional testing was performed in accordance with ISO 11070:2014 *Sterile single-use intravascular introducers, dilators and guidewires* and the FDA Guidance Document *Coronary and Cerebrovascular Guidewire Guidance* (January 1995). The following table summarizes the functional tests performed and test results obtained to demonstrate substantial equivalence to the predicate device.

Summaries of Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Visual Inspection	Tests per ISO 11070: Visual inspection for extraneous matter, process and surface defects or defects that may cause trauma to vessels during use	No extraneous matter, surface defects or visible droplets of coating were present on the CrossTorq 14 Guidewires.
Dimensional Verification	Tests per ISO 11070: Dimensional inspection per engineering drawings	All guidewires met dimensional specifications.
Flexing Test	Tests per ISO 11070: Inspection for defects and damage or flaking of the coating after flexing	No defects or damage / flaking of the coating were observed after flexing.
Tensile Strength	Tensile testing per ISO 11070	All guidewires met minimum clinically relevant force breakage requirements when tested according to ISO 11070.
Tip Shape, Retention	Guidewires must be shapeable and must retain shaped angle after simulated use	All tips met shaping and shape retention requirements after simulated use.
Torqueability	Measurement of torque response (average input to output lag) in an anatomical model	All guidewires demonstrated acceptable torque responses. The torque response of the subject device was comparable to that of the predicate device.
Torque Strength	Torque turns to failure in an anatomical model	All guidewires demonstrated acceptable torque strength. The torque strength of the subject device was comparable to that of the predicate device.

Summaries of Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Tip Flexibility	Measure force to deflect guidewire tips to 45 and 90 degrees at 5mm, 10mm, and 20mm test lengths	The forces required to deflect the guidewire tips of the softer CrossTorq 14 tip profiles were comparable to the forces required to deflect the Kinetix, while the forces required to deflect the tips of the stiffer CrossTorq 14 tip profiles were comparable to the forces required for the Boston Scientific Hornet 14 guidewire tips.
Fracture	Tests per ISO 11070: Inspection for fracture, loosening, or failure after wrapping around mandrel	No guidewires showed signs of fracture, loosening, or failure after wrapping them 8 times around a mandrel.
Coating Lubricity and Durability	Frictional force of coated guidewires was determined after simulated use in a tortuous path	All guidewires met specified frictional force requirements.
Coating Integrity	Coating uniformity and integrity visually examined on dyed samples after simulated use in a tortuous path	All samples showed acceptable coating coverage after simulated use.
Particulates	Particulates of various size ranges counted after simulated use in a tortuous path	All guidewires met specified number/size recovered particulate requirements.
Simulated Use Model Testing and Product Compatibility	Tortuous path model defined by ASTM F2394 Figure X2.4 used for simulated use testing Compatibility of the accessories with the CrossTorq 14 Guidewire was evaluated in the simulated tortuous path model evaluation.	Guidewires and predicate devices were found to perform acceptably in evaluations of: Torqueability in tortuous vasculature, Lubricity, Microcatheter and Balloon Catheter Support & Tracking, Compatibility with Introducer, Compatibility with Torque Device, and Compatibility with Microcatheter and Balloon Catheter.

Summaries of Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Column Buckling	Measure force to buckle the guidewire 1cm from the distal tip.	The forces required to buckle the guidewire tips of the softer CrossTorq 14 tip profiles were comparable to the forces required to deflect the Kinetix, while the forces required to buckle the tips of the stiffer CrossTorq 14 tip profiles were comparable to the forces required for the Boston Scientific Hornet 14 guidewire tips.
MRI Compatibility	Guidewires are constructed of metallic materials and should not be exposed to MRI procedures.	No testing performed. CrossTorq 14 Guidewires are labeled "MRI Unsafe."
Shelf Life	Device performance attributes that can be affected by storage conditions were evaluated after exposure to accelerated aging conditions per ASTM F1980.	After exposure to accelerated aging conditions simulating real-time storage under ambient conditions for 13 months, all device performance acceptance criteria were met, justifying labeling the devices with a 1-year shelf life.

CONCLUSION

Scientia Cardio Access, LLC has presented information in this premarket notification supporting its contention that the CrossTorq 14 Guidewire is substantially equivalent with respect to technological characteristics and indications for use to the predicate device.