March 15, 2019

Boston Scientific Corporation
Kevin Catalano
Sr. Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55311

Re: K190401
Trade/Device Name: MAMBA and MAMBA Flex Microcatheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 15, 2019
Received: February 19, 2019

Dear Kevin Catalano:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2019.03.15 16:24:23 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190401

Device Name
MAMBA and MAMBA Flex Microcatheters

Indications for Use *(Describe)*
The MAMBA and MAMBA Flex Microcatheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature, and can be used to exchange one guidewire for another.
The microcatheters are also intended to assist in the delivery of contrast media into the coronary 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
per 21 CFR §807.92

Sponsor:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Kevin Catalano Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2413 Fax: 763-494-2222 e-mail: kevin.catalano@bsci.com
Prepared	15 February 2019
Proprietary Name	MAMBA™ and MAMBA™ Flex Microcatheters
Common Name	Percutaneous Catheter
Product Code	DQY
Classification	Class II, 21 CFR Part 870.1250
Predicate Device	MAMBA™ and MAMBA™ Flex Microcatheters K171452 (21 Aug 2017)
Reference Device	Acuity Pro Guide catheter K171612 (30 Jun 2017)

Device Description

The MAMBA™ and MAMBA™ Flex devices (referred to as the "MAMBA Microcatheters") are designed to provide a platform for the user to exchange guidewires without losing their position in the vasculature.

The MAMBA device is available in a 135cm length, while MAMBA Flex is available in 135cm and 150cm lengths.

The MAMBA Flex models have a smaller outer diameter and a more flexible distal portion than the MAMBA device.

Marks on the proximal portion of the catheter shaft and a radiopaque marker at the distal tip facilitate placement of the device.

The device's inner lumen permits the use of 0.014 in./0.36 mm or smaller guidewires. The shaft consists of a coil which allows the device to be torqued to assist in advancement. The distal portion of the shaft is coated hydrophilic coating to assist in advancement.

The proximal end has a single luer hub for flushing or injecting through the inner lumen and is for guide wire lumen access during a guidewire exchange.

The MAMBA Microcatheters are to be used in patients where vessel conditions require additional wire support to reach the lesion and will deliver radiopaque media and therapeutic agents to selected sites in coronary vasculature.

Indications for Use / Intended Use

The MAMBA™ and MAMBA™ Flex Microcatheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature, and can be used to exchange one guidewire for another.

The microcatheters are also intended to assist in the delivery of contrast media into the coronary vasculature.

Comparison of Technological Characteristics

The MAMBA Microcatheters incorporate substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate, MAMBA Microcatheters, K171452.

Non-clinical Performance Data

Determination of substantial equivalence is based on an assessment of non-clinical performance bench testing data.

Bench Testing:

Bench testing was performed to evaluate physical integrity, functionality and performance of the MAMBA Microcatheters. Performance criteria includes: dimensional requirements, delivery and retraction, wire movement, shaft and manifold torque, wire lumen burst, tip bond, guidewire exchange, shaft flex and shaft kink, and dye flow.

The results of these tests provide reasonable assurance that the proposed device 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 testing; therefore, this device is considered to be substantially equivalent to the predicate device.

Conclusion

Based on the indications for use, technological characteristics, performance testing, the MAMBA Microcatheters have been shown to be appropriate for their intended use and are considered to be substantially equivalent to MAMBA Microcatheters, K171452.