510(k) Summary
per 21 CFR §807.92

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Prepared	16 May 2017
Proprietary Name	MAMBA™ and MAMBA™ Flex Microcatheters
Common Name	Percutaneous Catheter
Product Code	DQY
Classification	Class II, 21 CFR Part 870.1250
Predicate Device	ASAHI Corsair Microcatheter: K151103 (23 June 2015) K083127 (03 February 2009)
Reference Device	Renegade Hi-Flo Microcatheter K140329 (15 May, 2014)

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 device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the ASAHI Corsair Microcatheter, K151103 and K083127.

Performance Data

The MAMBA Microcatheters were subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010 (non-balloon component tests were applicable). Bench, animal and biocompatibility testing in accordance with ISO 10993 were performed to support a determination of substantial equivalence. 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 may be considered substantially equivalent to the predicate device.

Conclusion

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