Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Prerana Gurubasavaraj
Regulatory Affairs Specialist
9775 Toledo Way
Irvine, CA 92618

July 21, 2020

Re: K201690
Trade/Device Name: Mirage Hydrophilic Guidewire; X-pedion Hydrophilic Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX, MOF
Dated: June 18, 2020
Received: June 22, 2020

Dear Prerana Gurubasavaraj:

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,

Naira Muradyan, Ph.D.
Assistant Director (Acting)
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K201690

Device Name
Mirage™ Hydrophilic Guidewire; X-pedion™ Hydrophilic Guidewire

Indications for Use *(Describe)*
The Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

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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510(k) Summary
K201690

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration: 2029214
Contact Person:	Prerana Gurubasavaraj Specialist, Regulatory Affairs Telephone: (949) 297-5804 Email: prerana.gurubasavaraj@medtronic.com

Date Summary Prepared:	June 18 ,2020
Trade Name of Device:	Mirage™ Hydrophilic Guidewire
	X-pedion™ Hydrophilic Guidewire
Device Classification Name:	Guide, Wire, Catheter, Neurovasculature
Regulation Medical Specialty:	Cardiovascular
510(k) Review Panel:	Neurology
Classification Product Code:	DQX
Subsequent Product Code:	MOF
Regulation Number:	870.1330
Regulation Description:	Catheter Guide Wire
Device Classification:	Class II
Predicate Device:	Mirage™ and X-pedion™ Hydrophilic Guidewires 510(k): K193548
Reference Device:	React™ 68 Catheter 510(k): K180715

Device Description:
The Hydrophilic Guidewire is a stainless-steel guidewire with a radiopaque, platinum distal coil. The guidewire has a hydrophilic coating that spans the distal 170 cm. Included within the sterile pouch is a pin vise to assist in guidewire manipulation and an introducer needle to ease the introduction of the guidewire into the catheter hub and/or hemostasis valve.

Indication for Use Statement:
The Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

Device Comparison:

	Legally Marketed Predicate Device (K193548)	Mirage™ and X-pedion™ Hydrophilic Guidewires
Indication for Use Statement	The Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.	Same
Dimensions		
Nominal Wire Diameter	Mirage™: 0.008”	Same
	X-pedion™: 0.010”	Same
Device Length	200 cm ± 2.5 cm.	Same
Tip Length	10 cm	Same
Tip Type and Shape	Shapeable to 90°	Same
Coating Length	170 cm	Same
Material		
Coil	Platinum	Same
Wire	Stainless-Steel	Same
Coating	Hydrophilic	Same
Packaging		
Pouch	Polyester/Tyvek	Same
Carton	0.020” Solid Bleached Sulfate	Same
Accessories		
Pin Vise	Yes	Same
Introducer Needle	Yes	Same
Sterilization		
Method	Ethylene Oxide (EO)	Same
Stability		
Shelf Life	12 Months	36 Months

Performance Data – Bench:

The following non-clinical bench testing was performed to evaluate the performance of the Mirage™ and X-pedion™ Hydrophilic Guidewires. The successful results of the testing demonstrated that the changes do not raise questions of safety and effectiveness, supporting the substantial equivalence to the predicate device.

Test	Test Method Summary	Results
Performance		
Visual Inspection and Dimensional Verification	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per QP50324.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for visual inspection and dimensional verification.
Friction Force	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per TM0047.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for friction force.

Test	Test Method Summary	Results
Flexing	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ISO 11070.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for flexing.
Particulate	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per USP <788>.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for particulate.
Tensile Strength	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ISO 11070.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for tensile strength.
Corrosion Resistance	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ISO 11070.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for corrosion resistance.

Performance Data – Animal:
There is no change to the Indication for Use (IFU) Statement for the Mirage™ and X-pedion™ Hydrophilic Guidewires in comparison to the legally marketed predicate device. The differences in technological characteristics do not raise questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods.

Performance Data – Clinical:
There is no change to the Indication for Use (IFU) Statement for the Mirage™ and X-pedion™ Hydrophilic Guidewires in comparison to the legally marketed predicate device. The differences in technological characteristics do not raise questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods.

Conclusion:
There is no change to the Indication for Use (IFU) Statement for the Mirage™ and X-pedion™ Hydrophilic Guidewires in comparison to the legally marketed predicate device. In addition, the differences in technological characteristics do not raise questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods. The information provided in this submission supports a determination of substantial equivalence for the Mirage™ and X-pedion™ Hydrophilic Guidewires.