January 18, 2020

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Ryan Kenney
Manager, Regulatory Affairs
9775 Toledo Way
Irvine, California 92618

Re: K193548
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: MOF, DQX
Dated: December 18, 2019
Received: December 20, 2019

Dear Ryan Kenney:

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,

Xiaolin Zheng, Ph.D., M.S.
Director
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)*
K193548

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.

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510(k) Summary

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration: 2029214
Contact Person(s):	Prerana Gurubasavaraj Specialist, Regulatory Affairs Telephone: (949) 297-5804 Email: prerana.gurubasavaraj@medtronic.com
	Ryan Kenney Manager, Regulatory Affairs Telephone: (949) 297-5489 Email: ryan.j.kenney@medtronic.com

Date Summary Prepared:	January 17, 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(s):	Mirage™ and X-pedion™ Hydrophilic Guidewires 510(k): K124007
Reference Device(s):	React™ 68 Catheter 510(k): K180715 Meridian™ Guidewire 510(k): K093681

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 (K124007)	Mirage™ and X-pedion™ Hydrophilic Guidewires
Indication for Use Statement	The Exchange™, Mirage™, SilverSpeed™, X-celerator™, and X-pedion™ Hydrophilic Guidewires are 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.	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.
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	Equivalent
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	36 Months	12 Months

Biocompatibility:
The Mirage™ and X-pedion™ Hydrophilic Guidewires are categorized as external communicating devices contacting circulating blood for limited exposure (≤ 24 hours). The following biocompatibility testing was performed for the Mirage™ and X-pedion™ Hydrophilic Guidewires:

Test Description	Results	Conclusions
Chemical Characterization (Extractables/ Leachables)	None of the Chemical(s) of Potential Concern (COPC) for the test article present a risk to the patient.	The extractables/leachables found in Mirage™ and X-pedion™ Hydrophilic Guidewires are acceptable.
Cytotoxicity	The test article extract showed no evidence of causing cell lysis or toxicity in any of the test wells. The test article met the requirements of the test since the grade was less than Grade 2 (Mild).	The Mirage™ and X-pedion™ Hydrophilic Guidewires are considered non-cytotoxic.

Test Description	Results	Conclusions
Sensitization	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.	The Mirage™ and X-pedion™ Hydrophilic Guidewires do not elicit a sensitization response.
Irritation	The difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.0 for the sodium chloride and sesame oil test article extracts.	The Mirage™ and X-pedion™ Hydrophilic Guidewires are considered a non-irritant.
Acute Systemic Toxicity	There was no mortality or evidence of systemic toxicity from the extracts injected into the mice.	The Mirage™ and X-pedion™ Hydrophilic Guidewires do not indicate signs of toxicity.
Hemocompatibility	The hemolytic index for the test article in direct contact with blood was 0.5% and the hemolytic index for the test article extract was 0.6%.	The Mirage™ and X-pedion™ Hydrophilic Guidewires are considered non-hemolytic.
Hemocompatibility	The test article results were statistically significantly ($p<0.05$) lower than the negative reference material. The test article results were statistically significantly ($p<0.05$) greater than the control article. However, the test article results were within the historical range for an expected response of the negative reference material.	The control and test articles are not considered to be potential activators of the complement system.
Hemocompatibility	The thrombogenic potential of the control article was evaluated in comparison to the test article. In the absence of systemic anticoagulation, the test article has less thrombogenic potential in comparison to the control article.	The Mirage™ and X-pedion™ Hydrophilic Guidewires demonstrates moderate thrombus formation.
Pyrogenicity	No animal showed a temperature rise of 0.5°C or more above its baseline temperature. The total rise of the animal's temperature during the three (3) hour observation period was 0.5°C and within acceptable requirements.	The Mirage™ and X-pedion™ Hydrophilic Guidewires are considered non-pyrogenic.

The Mirage™ and X-pedion™ Hydrophilic Guidewires have been evaluated to meet requirements specified in ISO 10993-1.

Performance Data – Bench:

Non-clinical bench testing was used from the predicate device and newly performed to evaluate the performance of the Mirage™ and X-pedion™ Hydrophilic Guidewires.

The following non-clinical bench testing was completed for the predicate Mirage™ and X-pedion™ Hydrophilic Guidewires and justification was provided why these tests are still applicable to support the safety and performance of the modified devices:

Test	Test Method Summary	Results
Microbial		
Ethylene Oxide (EO) Residual	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ISO 10993-7.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for ethylene oxide residual.
Ethylene Chlorohydrin (ECH) Residual	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ISO 10993-7.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for ethylene chlorohydrin residual.
Bioburden Recovery	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ISO 11737-1.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for bioburden recovery.
Packaging		
Terminally Sterilized Medical Devices	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ISO 11607.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for packaging terminally sterilized medical devices.
Performance		
Device Compatibility/ Distal Access	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated to ensure the devices are compatible with ancillary devices to navigate through tortuous vessels.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for device compatibility/distal access.
Distal Flexibility	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated to ensure the devices navigate through tortuous vessels.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for distal flexibility.
Visual Fracture	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ISO 10555-1 and ISO 11070.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for visual fracture.
Radiopacity	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated to ensure the devices are clearly visible during use.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for radiopacity.
Tip Buckling	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated to ensure the devices withstand forces typical of clinical use.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for tip buckling.

Test	Test Method Summary	Results
Tip Retention	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated for tip retention.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for tip retention.
Tip Shapeability	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated for tip shapeability.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for tip shapeability.
Torque Response	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated to ensure the distal tip of the devices respond to manipulations made at the proximal end.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for torque response.
Turns to Failure	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated to ensure the devices withstand torsional forces typical of clinical use.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for turns to failure.

The following non-clinical bench testing was performed for the modified Mirage™ and X-pedion™ Hydrophilic Guidewires:

Test	Test Method Summary	Results
Microbial		
Bioburden	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ISO 11737-1.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for bioburden.
Bacterial Endotoxin	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated per ANSI/AAMI ST72, USP <161>, and USP <85>.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for bacterial endotoxin.
Performance		
Visual Inspection and Dimensional Verification	The Mirage™ and X-pedion™ Hydrophilic Guidewires were dimensionally evaluated.	The Mirage™ and X-pedion™ Hydrophilic Guidewires met the acceptance criteria for visual inspection and dimensional verification.
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 counts and sizes.
Friction Force	The Mirage™ and X-pedion™ Hydrophilic Guidewires were evaluated for friction force.	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.
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.
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.

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. Therefore, no new animal testing was needed.

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. Therefore, no clinical performance testing was needed.

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 Mirage™ and X-pedion™ Hydrophilic Guidewires are equivalent in terms of technological characteristics 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.