DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 12, 2016

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Ms. Jennifer Correa
Sr. Product Specialist/Regulatory Affairs
9775 Toledo Way
Irvine, California 92618

Re: K161152
Trade/Device Name: Navien Intracranial Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 6, 2016
Received: September 8, 2016

Dear Ms. Correa:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161152

Device Name
Navien™ Intracranial Support Catheter

Indications for Use *(Describe)*
The Navien™ Intracranial Support Catheter is indicated for the introduction of interventional devices into the peripheral and 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

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Jennifer Correa Senior Regulatory Affairs Specialist Telephone: (949) 297-9563 E-mail: jennifer.l.correa@medtronic.com
Date Summary Prepared:	September 6, 2016
Trade Name of Device:	Navien™ Intracranial Support Catheter
Common Name of Device:	Catheter, Percutaneous
Classification of Device:	21 CFR 870.1250 – Class II
Product Code:	DQY
Predicate Device:	Navien™ Intracranial Support Catheter, 510(k)#: K110055 Originally cleared under trade name: ReFlex™ Guide Catheter

Performance Data: The following testing was performed to support the coating change to the Navien™ Intracranial Support Catheter with new coating to establish substantial equivalence to the Navien™ Intracranial Support Catheter with old coating:

- Visual/Dimensional Inspection
- Torque Strength
- Coating Lubricity
- Catheter Leakage Test (Liquid)
- Dynamic Pressure Test
- Distal Tip Buckling
- Particulate Testing
- Physician Usability Testing

The following testing was leveraged from the predicate device due to sufficiency of the existing testing record and justification for adoption:

- System Dimensional- Length
- Kink Resistance
- Flow Rate During Continuous Flush (for information only)
- Leakage (Static Burst Test)

- Aspiration
- Labeling
- Catheter Hub (ISO 594-1)
- Tensile Srength
- Corrosion Resistance
- Tip Configuration
- Radiopacity

A Design Validation study was performed on a bench model to assess the substantial equivalence and usability of Navien™ Intracranial Support Catheter with new coating compared to the previously cleared Navien™ Intracranial Support Catheter with old coating. Biocompatibility testing, sterilization, and a 2-year accelerated aging study were also performed. No clinical studies were performed as there is no change to the indications for use or the fundamental scientific technology of the device.

Conclusion: The Navien™ Intracranial Support Catheter with new coating is substantially equivalent to the currently cleared Navien™ Intracranial Support Catheter with old coating based on the successful completion of non-clinical bench and design validation testing as well as identical principles of design, operation and indications for use.

Device Description:

The Navien™ Intracranial Support Catheter is a single lumen, flexible, variable stiffness composite catheter which has a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. The Navien™ Intracranial Support Catheter has a marker on the distal tip that is visible under fluoroscopy. The dimensions are included in the device label. The Navien™ Intracranial Support Catheter inner lumen can accommodate guidewires up to 0.038 inches in diameter to aid in placement of the catheter system. The catheter has both straight and pre-shaped tips.

The proximal end of the Navien™ Intracranial Support Catheter has a Luer fitting to allow attachment of accessories and infusion of liquids through the system. The Catheter is offered in various sizes to accommodate physician preferences and anatomical variations. The catheter is provided sterile, non-pyrogenic, and is intended for single use only.

Indications for Use:

The Navien™ Intracranial Support Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

Device Comparison

The table below provides a comparison of the technological characteristics of the Navien™ Intracranial Support Catheter with old coating and the currently cleared Navien™ Intracranial Support Catheter.

	Navien™ Intracranial Support Catheter with old coating **(K110055)**	**Navien™ Intracranial Support Catheter with new coating**
Indication for Use	The Navien™ Intracranial Support Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.	Same
Catheter Shaft Materials	PTFE lined polymeric catheter, with hydrophilic coating	Same
Catheter Shaft Support	Nitinol	Same
Marker band	Platinum	Same
Usable Length	90 – 130 cm	Same
Distal ID	0.046" – 0.072"	Same
Distal OD	0.058"– 0.084" max	Same
Proximal ID	0.046" – 0.072"	Same
Proximal OD	0.058"– 0.084" max	Same
Tip Configuration	Single, straight flexible tip	Same
Sterilization Method	Ethylene Oxide	Same
Packaging	Catheter in polyethylene hoop attached to packaging card inside PET/PE/Tyvek pouch inside SBS carton	Same

Sterilization and Shelf Life

The packaged Navien™ Intracranial Support Catheter with new coating is sterilized using a validated ethylene oxide (EO) sterilization cycle at the Sterigenics US; LLC facility located at 4900 Gifford Avenue, Los Angeles, CA. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135-1:2007, *Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.*

Aging studies for the Navien™ Intracranial Support Catheter with new coating device has established the product and packaging remain functional and maintain sterility for up to 24 months. Aging studies for packaging integrity, seal strength, and device functionality were performed and met all acceptance criteria.

Biocompatibility

Biocompatibility testing was performed in compliance with the FDA consensus standard, recognition number 2-156, AAMI/ANSI/ISO 10993-1: 2009, Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process and U.S. Food and Drug Administration (FDA)

Blue Book Memorandum G95-1 (1995) guidelines. All studies were conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part 58.

Test	Result	Conclusion
Plastics (USP)	Meets USP Physicochemical extraction parameters.	Passes physical chemical characteristics.
L929 MEM Elution Test – ISO	The test article scored "0" at 24, 48 and 72 ± 4 hours and is considered non-cytotoxic under the conditions of this test.	Non-cytotoxic
Klingman Maximization Test – ISO (Guinea Pig Sensitization)	Under the conditions of this protocol, the test article did not elicit a sensitization response.	Non-sensitizer
Intracutaneous Injection Test - ISO	The differences in the mean test and control scores of the extract dermal observations were less than 1.0, indicating that the requirements of the ISO Intracutaneous Reactivity Test have been met by the test article.	Non-irritant
Acute Systemic Injection Test – ISO	None of the test article extract treated animals were observed with clinical signs consistent with toxicity at any of the observation periods.	Non-cytotoxic
Materials Mediated Rabbit Pyrogen – ISO	This response did not exceed the USP limit and meets the requirements for this test. Therefore these results indicate that the test article was determined to be non-pyrogenic.	Non-pyrogenic
Hemolysis: Direct Contact / Indirect Extract	There were no significant differences between the test article extract and negative control article results. The test article is considered non-hemolytic	Non-hemolytic
Complement activation C3a and SC5b-9	The levels of C3a and SC5b-9 of the Navien™ catheter with new coating are comparable to the Navien™ with old coating and less than that of the positive control.	Levels of the compliments C3a and SC5b complements were similar for Navien and control device
Thrombosis (*in vivo*) – Canine (Navien)	The thromboresistance properties of the Navien™ Intracranial Support Catheters are acceptable in clinical use.	Acceptable, expected to be equivalent to Navien in clinical use

Test	Result	Conclusion
in vitro Hemocompatibility Assay	The Navien Guide Catheter did not result in a decrease in any blood component as compared to the reference material. These results indicate that the cause of thrombi is not related to the materials exposed to human blood during use.	No adverse effect on platelet and leukocyte counts
Partial Thromboplastin Time	Clotting times for the Navien (predicate device) test arms were similar to the negative control and the reference material (HDPE), indicating that the device materials are not an activator of the intrinsic coagulation pathway.	No adverse effect on prothrombin coagulation time of human plasma.
Ames bacterial Mutagenicity 4 salmonella+1e.coli	Based on the criteria and conditions of the study protocol, the test article is considered non-mutagenic.	Non-mutagenic
in vitro Mouse Lymphoma Assay with Extended Treatment	The test article is considered to be non-mutagenic (non-genotoxic and non-clastogenic) in this test system.	Non-mutagenic
in vivo Mouse Micronucleus Assay	Based on the criteria of the assay, the test article is considered non-mutagenic in this test system.	Non-mutagenic

Performance Testing – Bench

A summary of the pre-clinical bench testing performed for the Navien™ Intracranial Support Catheter is presented in the table below.

Test	Method	Acceptance Criteria	Conclusions
Dimensional Inspection	The usable length, proximal and distal inner and outer diameters were measured and recorded.	Usable length, proximal and distal inner and outer diameters must meet all inspection criteria	All device met acceptance criteria.
Torque to Failure	Device was tested for full-length torque strength to determine number of rotations to failure.	The catheter must withstand multiple revolutions without failure	Torque to failure testing met acceptance criteria.
Coating Lubricity/Durability	Device coating was evaluated for average frictional force and durability.	Average Friction Force must be comparable to the predicate device	Coating lubricity and durability testing met acceptance criteria.
Liquid Leakage	Device was tested for ISO 10555-1, Annex C liquid leakage testing.	Catheter shall not leak per ISO 10555-1	Liquid leakage met acceptance criteria.
Dynamic Burst	Device was tested under full-length static conditions to burst and at pressures experienced during worst-case dynamic injections.	Catheter shall not burst or leak during a dynamic pressure test	Dynamic burst testing met acceptance criteria.
Tip Buckling	Repeated distal tip buckling force under compressive load was evaluated for stiffness.	Compressive load shall not be statistically significantly different to comparable and/or the predicate device	Tip buckling force met acceptance criteria.
Particulate Testing	Device was evaluated for particulate generation under simulated use in a representative tortuous anatomical model per USP<788>	Particulate must be within limits per USP<788>	Number of particulates generated met acceptance criteria.
Physician Usability Testing	The device was navigated through a tortuous benchtop model to assess accessibility and the tip atraumatic profile.	Assess navigation of Navien™ with new coating to the ICA and comparing Navien™ with new to Navien™ with old coating with regards to tip atraumaticity.	All test results met the acceptance criteria.

Performance Testing - Animal

No animal study was performed as there is no change to the indications for use or the fundamental scientific technology for the new device. Substantial equivalence of the Navien™ Intracranial Support Catheter with new coating has been established to the predicate device through the results of bench testing.

Performance Testing – Clinical

No clinical study was performed as there is no change to the indications for use or the fundamental scientific technology for the new devices. Substantial equivalence of the Navien™ Intracranial Support Catheter with new coating has been established to the predicate device through the results of bench and design validation testing.