June 2, 2022

Kai Medtech, LLC
Ricardo Olivo
Senior Director, Quality and Reguatory Affairs
22651 Lambert Street, Suite 107
Lake Forest, California 92630

Re: K212288
Trade/Device Name: Minjie Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: April 29, 2022
Received: May 3, 2022

Dear Ricardo Olivo:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212288

Device Name
Minjie Catheter System

Indications for Use *(Describe)*
The Minjie Catheter System is indicated for the introduction of interventional devices into the peripheral and neruovasculature.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K212288

This 510(k) Summary for the Minjie Catheter System is submitted in accordance with the requirements of 21 CFR Part 807.92 and following the recommendations outlined in FDA guidance, "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*," issued on July 28, 2014.

Submitter

Submitter:	Kai Medtech, LLC 22651 Lambert Street, Suite 107 Lake Forest, CA 92630 USA
Contact Person:	Ricardo Olivo Senior Director, Quality and Regulatory Affairs +1 (949) 767-8960, Extension 109 ricardo.olivo@kaimtgroup.com
Date Prepared:	June 01, 2022

Device Name and Details

Trade Name of Device:	Minjie Catheter System
Common Name of Device:	Distal Access Catheter
Device Classification:	Class II
Device Classification Name:	Percutaneous Catheter
Regulation Number/ Description:	21 CFR 870.1250, Percutaneous Catheter
Classification Product Code:	Primary Product Code: QJP Secondary Product Code: DQY
Review Panel:	Neurology

Table 1: Legally Marketed Predicate and Reference Devices

510(k) Number	Product Code	Trade Name of Device	Device Manufacturer
Predicate Device			
K150107	DQY	Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Reference Devices			
K161152	DQY	Navien Intracranial Support Catheter	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
K140080	DQY	ENVOY® Distal Access (DA) Guiding Catheter	Codman & Shurtleff, Inc.

Device Description

The Minjie Catheter System consists of the Minjie Catheter, Introducer Peel Away Tool and packaging hoop with Elbow Flush Luer. The Minjie Catheter is a single lumen, flexible, variable stiffness composite catheter with a Nitinol structure. A radiopaque marker band on the distal tip of the catheter is used for visualization under fluoroscopy. The distal section of the catheter is coated with a hydrophilic coating, to reduce friction during intravascular use. The Minjie Catheter System dimensions are included in the individual device label. The devices are supplied sterile and are intended for single use only.

Indications for Use Statement

The Minjie Catheter System is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

Comparison of Technological Characteristics with the Predicate Device

A comparison of the technological characteristics of the subject device (Minjie Catheter System) and predicate device (Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter) demonstrates that the technological characteristics of the subject Minjie Catheter System are substantially equivalent to the technological characteristics of the predicate Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter previously cleared under K150107. Refer to Table 2 below for a comparison between the Minjie Catheter System and Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter.

Table 2: Comparison between Minjie Catheter System and Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter.

	Predicate Device, Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter (K150107)	**Subject Device, Minjie Catheter System (K212288)**	**Comparison**
Regulation	DQY (21 CFR 870.1250)	QJP, DQY (21 CFR 870.1250)	Similar
Indications for Use Statement	The Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter are indicated for the introduction of interventional devices into the peripheral and neurovasculature.	The Minjie Catheter System is indicated for the introduction of interventional devices into the peripheral and neurovasculature.	Same
Function / Principle of Operation	Facilitate introduction and selective placement of interventional devices into target blood vessels in the peripheral and neuro vasculature.	Facilitate introduction and selective placement of interventional devices into target blood vessels in the peripheral and neuro vasculature	Similar
Catheter Shaft Materials	PTFE lined polymeric catheter with hydrophilic coating	PTFE lined polymeric catheter with hydrophilic coating	Similar
Catheter Shaft Support	Nitinol	Nitinol	Similar
Marker Band	Platinum	Platinum/Iridium	Testing demonstrated that the difference does not raise new questions of safety and effectiveness.
Usable Length	132cm – 135cm	115cm – 131cm	Similar
Coating Length	40cm – 45cm	60cm	Testing demonstrated that the difference does not raise new questions of safety and effectiveness.
Distal Inner Diameter (ID)	0.061”	0.068” (1.73mm)	Testing demonstrated that the difference does not raise new questions of safety and effectiveness.
Distal Outer Diameter (OD) (Max)	0.071”	0.081” (2.06mm)	Testing demonstrated that the

			difference does not raise new questions of safety and effectiveness.
Proximal ID	0.069”	0.068” (1.73mm)	Similar
Proximal OD (Max)	0.082”	0.083” (2.11mm)	Similar
Shaft	Progressively softer from proximal end to distal tip	Progressively softer from proximal end to distal tip	Similar
Tip Configuration	Single, straight flexible tip	Single, straight flexible tip	Similar
Guidewire Compatibility	Can be navigated over guidewire with maximum OD of 0.038”	Can be navigated over guidewire with maximum OD of 0.035”	Testing demonstrated that the difference does not raise new questions of safety and effectiveness.
Packaging	Catheter in polyethylene hoop attached to packaging card inside PET / PE / Tyvek pouch inside SBS carton	Catheter in polyethylene hoop attached to packaging card inside PET / PE / Tyvek pouch inside SBS carton	Similar
Accessories	Introducer Tool	Introducer Peel Away Tool	Testing demonstrated that the difference does not raise new questions of safety and effectiveness.
Sterilization Method	Ethylene oxide (EO) gas	EO gas	Similar

Performance Data (Non-Clinical Testing)

Sterilization and Shelf-Life

The packaged Minjie Catheter System is sterilized using a validated EO sterilization cycle. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135:2014, “*Sterilization of health care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices*.”

Endotoxin testing was conducted in accordance with FDA guidance, “*Pyrogen and Endotoxins Testing: Questions and Answers,*” issued in June 2012.

Aging studies for the Minjie Catheter System have established that the product remains functional, and packaging maintains sterility for up to twenty-four months. Aging studies for packaging integrity and product stability (device functionality) were performed and met all acceptance criteria.

Biocompatibility Testing

Biocompatibility testing was performed in accordance with FDA guidance, “*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part*

1: Evaluation and testing within a risk management process"," issued on September 4, 2020, and ISO 10993-1:2018, "*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*," for the Minjie Catheter System categorized as a limited exposure (< 24 hours), external communicating device contacting circulating blood. Refer to Table 3 below for summary of the test results.

Table 3: Summary of Biocompatibility Testing Results

Test Standard and Study Name	Test Results	Conclusions
Cytotoxicity per ISO 10993-5; ISO Elution Method	The test article extract met the requirements of the test because the grade was less than a grade 2 (mild reactivity).	Non-cytotoxic
Sensitization per ISO 10993-10; ISO Guinea Pig Maximization Sensitization Test	Animals tested with the test extract did not show evidence of delayed dermal contact sensitization.	Non-sensitizer
Intracutaneous Irritation per ISO 10993-10; ISO Intracutaneous Study in Rabbits	Animals tested with the test extract exhibited similar edema and erythema scores compared to the negative control.	Non-irritant
Acute Systemic Toxicity per ISO 10993-11; ISO Acute Systemic Toxicity Study in Mice	No animals injected with the test article showed a significantly greater biological reaction than the animals treated with the control article.	No acute systemic toxicity
Material Mediated Pyrogen per ISO 10993-11; USP Rabbit Pyrogen Study, Material Mediated	No single animal showed a temperature rise of ≥ 0.5°C above its baseline temperature. Total rise of rabbit temperatures during three (3) hour observation period was within acceptable USP requirements. The test article met the requirements for the absence of pyrogens.	Non-pyrogenic
Hemocompatibility per ISO 10993-4; ASTM Hemolysis Study	The hemolytic index for the test article in direct contact with blood was 0.0%, and for test article extract was 0.7%.	Non-hemolytic
Hemocompatibility per ISO 10993-4; SC5b-9 Complement Activation Assay	SC5b-9 Concentration of the test article was not statistically different than activated non-human serum control.	Non-activator of the complement system
Hemocompatibility per ISO 10993-4; ASTM Partial Thromboplastin Time (PTT) with Sponsor Provided Control	Inactivated partial thromboplastin time test was conducted, and the results showed no different compared to the reference device, ENVOY ® Distal Access (DA) Guiding Catheter, K140080.	Non-activator of coagulation
Platelet and Leukocyte Counts (Platelet Adhesion)	The leukocyte and platelet counts that were exposed to the negative control,	Non-activator of platelet and

per ISO 10993-4: 2017	subject device and predicate device (Arc™ Intracranial Support Catheter, K150107) extracts did not show difference.	leukocyte

Bench Testing

A summary of the non-clinical bench testing performed for the Minjie Catheter System is presented in Table 4 below.

Table 4: Summary of Bench Testing Results

Test Name	Test Method Summary	Results
Catheter Visual Inspection	Fully assembled devices were inspected with an unaided eye for dents, kinks, cracks or other damage or anomalies that may impact function of device.	All devices met acceptance criteria.
Coating Integrity	Fully assembled devices were inspected under a minimum 40X magnification before and after simulated use and particulate testing, for coating defects.	All devices met acceptance criteria.
Particulate Testing	The device was evaluated for particulate generation under simulated use in a representative tortuous anatomical model.	All devices met acceptance criteria.
Simulated Use	The device was repeatedly navigated through a tortuous benchtop model to assess compatibility with accessories and interventional devices including guidewire, guide catheter, microcatheter and stent retriever, and assess device stability and ability to navigate to the M1 and M2 segments of the middle cerebral artery (MCA).	All devices met acceptance criteria.
Coating Frictional Forces / Durability	Device coating was evaluated for frictional forces, and durability via repeated navigation through simulated use test model.	All devices met acceptance criteria.
Distal Tip Buckling	Tip buckling was evaluated, including testing the distal tip under compressive loads at 5 mm, 10 mm and 20 mm from the distal tip, to evaluate stiffness of the distal tip.	All devices met acceptance criteria.
Kink Resistance	The device was wrapped around several mandrels of clinically relevant diameters and inspected for kinks.	All devices met acceptance criteria.
Liquid Leakage under pressure	The device was tested for liquid leakage under pressure per ISO 10555-1, Annex C.	All devices met acceptance criteria.
Hub Air Aspiration Leak	The device was tested per ISO 10555-1, Annex D for hub air aspiration leak.	All devices met acceptance criteria.
Torque to Failure	The device was tested in a simulated use test model for full-length torque strength to determine the	All devices met acceptance criteria.

Test Name	Test Method Summary	Results
	number of rotations to failure.	
Manual Injection / Peak Pressure	The device was tested for full-length, after simulated use testing, using manual syringe injection of worst-case contrast media, to verify that device can withstand pressures that may be generated during manual delivery of contrast media.	All devices met acceptance criteria.
Static / Dynamic Burst	The device was tested under full-length static conditions to burst using worst-case contrast media per ISO 10555-1, Annex F, and compared against burst pressures exhibited during manual syringe injection of contrast media.	All devices met acceptance criteria.
Luer Hub Compatibility	Luer hub testing was performed per ISO 80369-7 and ISO 80369-20.	All devices met acceptance criteria.
Dimensional Inspection	The usable length, proximal and distal inner and outer diameters were measured and recorded.	All devices met acceptance criteria.
Lumen Patency	The total length of the device must allow to pass a mandrel of the required size from the proximal hub to distal tip.	All devices met acceptance criteria.
Shaft Peak Tensile Force	Shaft peak tensile strength was tested to failure at the distal tip section, and each joint of the device, per ISO 10555-1, Annex B test methods.	All devices met acceptance criteria.
Hub Peak Tensile Force	Hub-shaft joint peak tensile strength was tested to failure, per ISO 10555-1, Annex B test methods.	All devices met acceptance criteria.
Physician Usability Testing	The device was navigated through a tortuous benchtop model to assess compatibility with accessories, device stability, ability to inject saline, and the user's ability to navigate to the M1 and M2 segments of the MCA.	All devices met acceptance criteria.

Animal Testing

An animal study was performed to verify the safety and validate the functionality of the Minjie Catheter System in comparison to the predicate device, Arc™ Intracranial Support Catheter. The Minjie Catheter System yielded acceptable usability criteria ratings to validate functionality. As confirmed by angiographic and histological evaluations, the Minjie Catheter System was verified to be safe for its intended use.

Clinical Testing

No clinical testing was conducted. The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods.

Conclusion

The Minjie Catheter System has the same intended use as the predicate device and the technological characteristics are similar to the predicate device. The differences do not raise new questions of safety and effectiveness. The information and testing presented in this 510(k) submission demonstrate that the Minjie Catheter System is substantially equivalent to the predicate device, Arc™ Intracranial Support Catheter, for use in the peripheral and neurovasculature.