May 31, 2022

Guangzhou Easycess Medical Co., Ltd
Xingcheng Liu
Manager of Registration Affairs Department
Room 701, Building B4, 11 Kaiyuan Avenue, Huangpu District,
Guangzhou, 510530
China

Re: K213065
Trade/Device Name: Distal Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: April 28, 2022
Received: May 5, 2022

Dear Xingcheng Liu:

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)*
K213065

Device Name
Distal Access Catheter

Indications for Use *(Describe)*
The Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic agents or therapeutic devices. It is not intended for use in coronary arteries.

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
K213065

I. SUBMITTER

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Phone: 020-31603990
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Contact Person: Xingcheng Liu
Date of Preparation: May 30th, 2022

II. DEVICE

Name of Device: Distal Access Catheter
Common or Usual Name: Distal Access Catheter
Classification Name: Percutaneous catheter (21 CFR 870.1250)
Regulatory Class: II
Product Code: QJP, DQY

III. PREDICATE DEVICE

Primary predicate device: SOFIA PLUS/Distal Access Catheter (K150366)
Secondary predicate device: SOFIA Distal Access Catheter (K131482, K142014)
These predicate devices have not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Distal Access Catheter consists of a catheter and accessories (hemostatic valve, introducer sheath, and a shaping mandrel). The catheter is a single-lumen, flexible catheter designed with coil and braid reinforcement. The distal segment is steam-shapeable, and a hydrophilic coating is applied for navigation of the catheter through the vasculature. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy.

The catheter body is constructed with a stainless-steel coil (less 2 cm of the catheter length) over the inner lumen liner comprised of polytetrafluoroethylene (PTFE). To provide additional shaft support, a stainless-steel wire braiding has been added over the stainless-steel coil from the proximal end to distal end. A platinum/iridium alloy radiopaque marker band is located at the distal tip of the catheter. An outer layer of varying durometers and lengths of polyamide (PA), polyether block amide (Pebax) and polyurethane (PU) covers the entire catheter body from proximal to distal end, respectively.

A hub (PC) is attached to the proximal end of the catheter. A strain relief made from polyether block amide (Pebax) is placed at the proximal end of the catheter and distal

end of the hub. The hub-strain relief provides for the kink resistance for the proximal end. A luer fitting on the catheter hub is used for the attachment of accessories.

The outer surface of the catheter (distal 60 cm) is coated with a hydrophilic coating to reduce friction during navigation in the vasculature.

A shaping mandrel (stainless steel, 80 mm in length) is provided with the catheter to be used by the physician for tip shaping. An introducer sheath (PTFE) is included to facilitate the introduction of the catheter into guide catheters during clinical use. A hemostatic valve is used to connect to the proximal section of the catheter.

The Distal Access Catheter is provided sterile and for single use only. The catheter is placed in a dispenser tube (HDPE) and is placed on a packaging card (HDPE) that is provided in a sterile barrier PET/PE film and Tyvek pouch and placed in a carton box.

V. INDICATIONS FOR USE

The Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic agents or therapeutic devices. It is not intended for use in coronary arteries.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technological Comparison:

Device name		SOFIA PLUS/Distal Access Catheter (K150366, Primary predicate device)	SOFIA Distal Access Catheter (K131482, K142014, Secondary predicate device)	Distal Access Catheter (K213065, Subject device)
Intended Use		The SOFIA PLUS /Distal Access Catheters are indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.	The SOFIA Distal Access Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.	The Distal Access Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic agents or therapeutic devices. It is not intended for use in coronary arteries.
Material	Catheter inner layer	PTFE, polyolefin elastomer	PTFE, polyolefin elastomer	PTFE
	Catheter middle layer	Stainless steel braid/coil	Stainless steel braid/coil	Same
	Catheter outer layer	Polyurethane elastomer, polyether block amide (Pebax) and polyamide	Polyurethane elastomer, polyether block amide (Pebax) and polyamide	Same
	Marker	Platinum/Iridium	Platinum/Iridium	Same
	Hub	Nylon	Nylon	PC

Device name		SOFIA PLUS/Distal Access Catheter (K150366, Primary predicate device)	SOFIA Distal Access Catheter (K131482, K142014, Secondary predicate device)	Distal Access Catheter (K213065, Subject device)
	Strain Relief	Polyurethane	Polyurethane	Pebax
	Introducer	Pebax	Pebax	PTFE
	Shaping Mandrel	Stainless steel	Stainless steel	Same
	Hemostatic Valve	Not applicable	Not applicable	PC
Catheter Size		6F	5F	5F 6F
Inner Diameter (ID)		0.070 inch (1.78 mm)	0.055 inch (1.4 mm)	5F: 0.056"（1.42mm） 6F: 0.071"（1.80mm）
Outer Diameter (OD)		0.0825 inch (2.1 mm)	0.068 inch (1.7 mm)	5F: 0.068"（1.73mm） 6F: 0.083"（2.11mm）
Effective Length		115-135 cm	115-125 cm	115-135cm
Coating		Hydrophilic coating (Hydak®)	Hydrophilic coating (Hydak®)	Hydrophilic coating (Polyamide)
Tip Configuration		Steam shapeable by user	Steam shapeable by user	Same
Guidewire Compatibility		0.035 inch	0.035 inch or 0.038 inch	0.035 inch
Accessories		Introducer sheath and shaping mandrel	Introducer sheath and shaping mandrel	Introducer sheath, shaping mandrel and hemostatic valve
Method of Supply		Sterile and single use	Sterile and single use	Same
Sterilization Method		Ethylene Oxide	Ethylene Oxide	Same
Packaging Configuration		Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer and shaping mandrel placed on a polyethylene packaging card that is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box.	Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer and shaping mandrel placed on a polyethylene packaging card that is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box.	Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer, shaping mandrel and hemostatic valve placed on a polyethylene packaging card that is inserted into a Tyvek/PE/PET pouch. Pouch and IFU placed in bleached sulfate carton box.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

- **Bench Testing and Sterility**

The bench testing of the Distal Access Catheter was performed using the applicable sections of the ISO 10555-1 international standard for sterile, single-use intravascular catheters. The testing demonstrates that the in vitro behavior of the device is well characterized within design specifications. The results of bench testing and sterility

evaluation are listed in the table below:

Test	Specification	Conclusion
Surface Inspection	The external surface of the catheter shall be free from extraneous matter. The external surface of the catheter, including the distal end, shall be free from process and surface defects which could cause trauma to vessels during use.	The surface integrity is suitable for intended clinical use.
Surface Contamination	The test article shall be free from surface contaminants from uncured coating surface particulates > 0.02 mm^2, embedded particulates. The distal tip shall be smooth and tapered. PTFE inner layer not delaminated.	The surface integrity is suitable for intended clinical use.
Dimensional Verification	The device shall meet the specified dimensional requirements, including catheter OD, catheter ID, effective length, length of distal tip and total length of accessories.	The device met the dimensional and physical specifications.
Distal Tip	The distal tip shall be smooth, rounded, tapered, or similarly finished to minimize trauma to vessels during use.	Distal tip is suitable for intended clinical use.
Radio Detectability	The tip of the catheter should be visible under fluoroscopy.	Device radiopacity is suitable for intended clinical use.
Corrosion Resistance	Metallic components of the catheter intended for fluid path contact shall show no signs of corrosion.	Corrosion resistance is suitable for intended clinical use and met requirements of ISO 10555-1.
Peak Tensile Force	6F Catheter force at break ≥15N for distal section and hub/catheter junction. 5F Catheter force at break ≥10N for distal section and hub/catheter junction.	Peak tensile force is suitable for intended clinical use and met requirements of ISO 10555-1.
Fluid leakage at ＞ 46 psi	No liquid leakage from hub and catheter shaft at 46 psi for 30 seconds.	Device integrity is suitable for intended clinical use and met requirements of ISO 10555-1.
Air Leakage	No air leakage at hub into syringe when negative pressure was applied for 15 seconds.	Device integrity is suitable for intended clinical use and met requirements of ISO 10555-1.
Guaging	The plane of the maximum diameter at the opening of the female conical fitting shall lie between the two limit planes of the gauge.	The device hub met the requirements of ISO 80369-7.
Separation Force	The mating parts separation force is greater than 35 N.	The device hub met the requirements of ISO 80369-7.
Unscrewing Torque	Test article luer remains attached after applying an unscrewing torque not less than 0.02 N·m for a minimum of 10 seconds.	The device hub met the requirements of ISO 80369-7.
Stress Cracking	No stress cracks on the test article hub.	The device hub met the requirements of ISO 80369-7.
Ease of Assembly	Components fit together securely with no resistance observed between the test article luer and reference fitting.	The device hub met the requirements of ISO 80369-7.
Resistance to Overriding	Test article luer does not override reference fitting threads.	The device hub met the requirements of ISO 80369-7.
Particulate	The amount of particulate matter that comes off the device during simulated use testing shall be determined and compared to the predicate device.	The amount and size of particles from the subject device was comparable to the predicate device.
Static Burst Pressure	The catheter was tested to evaluate the burst pressure under static conditions per ISO 10555-1:2013(E) Annex F.	Device integrity is suitable for intended clinical use and met requirements of ISO 10555-1.
Coating	The catheter was tested 20 times on the friction	Device tracks easily with no

Lubricity and Durability	tester. The frictional force shall be equivalent to the predicate device and be less than 0.3N.	coating cracking or separation, and is equivalent to the predicate device.
Equipment Interface	The catheter shall be compatible with 0.035" guidewire, ≥ 0.088" ID guide catheter/ introducer sheath, ≤ 0.027" OD microcatheters, and common hemostatic valve.	The device is compatible with the accessories as specified.
Tip Shapeability	The distal tip should be steam shapeable and equivalent to the predicate devices.	Shapeability of the distal tip after steam shaping is equivalent to predicate device.
Kink Resistance	No kinks when wrapped around pin gauges of clinical use relevant radii. No kinks noted during simulated use testing. Shall be equivalent to the predicate devices.	The device is resistant to kinking around relevant radii turns.
Simulated Use	The catheter should reach various target locations in the tortuous vessel model; the catheter could be delivered and retracted smoothly with a 0.035" guidewire in the model; no device damage or defects after simulated use.	Device performs as intended under simulated use conditions.
Torque Response	The torque response of the catheter should be no worse than the predicate device.	Device torque response is equivalent to the predicate device.
Torque Strength	No catheter breakage after 50 rotations.	Device torque strength is equivalent to the predicate device.
Pushability/ Retractability	The pushability/retractability of the catheter in the tortuous vessel model shall be not worse than the predicate device.	Device pushability/ retractability is equivalent to the predicate device.
Catheter Stiffness	The catheter stiffness shall be equivalent to the predicate devices.	The catheter stiffness is equivalent to the predicate device.
Catheter Flexural Fatigue	No flexural fatigue following repeated bending during simulated use testing and repeated hoop stress following pressure and air aspiration testing.	The catheter flexural fatigue is equivalent to the predicate device.
Dynamic Burst	The catheter shall not burst under dynamic pressure of 300 psi for 30 seconds.	The device met the test acceptance criteria.
Flow Rate	The catheter should withstand manual injection of contrast media and saline at the clinically relevant flow rates.	The device can withstand flow rates suitable for intended clinical use.
Ethylene Oxide Residue	The residual amount of ethylene oxide in a single package should not exceed 10μg/g.	Ethylene Oxide Residue met the acceptance criteria per ISO 10993-7:2008.
Sterility	The product shall be sterile.	Sterility of the catheter met the acceptance criteria per ISO 11135:2014.
Bacterial Endotoxins	Endotoxin content shall not be greater than 2.15 EU/ kit.	Bacterial endotoxins met the acceptance criteria per USP <85>.

- **Biocompatibility**

The biocompatibility evaluation for the Distal Access Catheter was conducted in accordance with FDA's biocompatibility guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"."

The biological tests were conducted in compliance with the Good Laboratory Practice (GLP) Regulation 21 CFR 58. The results of testing are listed in the table below:

Biocompatibility Test	Result	Conclusion
Cytotoxicity Test（ISO 10993-5） MTT Method, MEM with 10% FBS extract	The cell viability of 100% test article extract was 95.5%.	Non-cytotoxic
Skin Sensitization Test（ISO 10993-10） Guinea Pig Maximization Test, 0.9% Sodium Chloride Injection Extract and Sesame Oil Extract	The positive rate of the test article was 0%.	No significant evidence of skin sensitization
Intracutaneous Reactivity Test（ISO 10993-10） 0.9% Sodium Chloride Injection Extract and Sesame Oil Extract	The final test article score was calculated to be 0.	Non-irritant
Acute Systemic Toxicity Test（ISO 10993-11） Intravenous 0.9% Sodium Chloride Injection Extract and Sesame Oil Extract	Body weight data were acceptable and equivalent between the corresponding test and control treatment groups.	No significant evidence of systemic toxicity
Acute Systemic Toxicity Test（ISO 10993-11） Intraperitoneal Sesame Oil Extract	Body weight data were acceptable and equivalent between the corresponding test and control treatment groups.	No significant evidence of systemic toxicity
Hemolytic Properties Test (ASTM F756) Direct and Extract Contact Method Rabbit Blood	The hemolysis index was 0.44% (direct contact) and 0.00 (indirect contact).	No influence on hemolytic properties
Partial Thromboplastin Time (PTT) Test (ISO 10993-4) In vitro Human Blood	No significant differences between the sample group and the negative group.	No effect on PTT
In Vivo Thrombogenicity Test（ISO 10993-4） Non-anticoagulated venous implant (NAVI) Model	No significant differences between the test and control articles.	Equivalent to the control article
Pyrogen Test（ISO 10993-11） 0.9% Sodium Chloride Injection Extract Rabbit	No rabbit shows an individual rise in temperature of 0.5 ℃ or more.	Non-pyrogenic
Complement Activity (C3a, SC5b-9) Test (ISO 10993-4) In vitro Test	No significant difference between the sample group and negative control group.	Equivalent to the negative control group

VIII. CONCLUSIONS

The data presented in this submission demonstrate the technological similarity and substantial equivalence of the Distal Access Catheter when compared with the predicate devices SOFIA PLUS/Distal Access Catheter(K150366) and SOFIA Distal Access Catheter (K131482, K142014).

The subject and predicate devices,

- have the same indications for use,
- use the same operating principle,
- incorporate the same basic design,
- are packaged and sterilized using similar materials and processes.

In summary, the Distal Access Catheter described in this submission is substantially equivalent to the predicate devices.