January 7, 2022

Agile Devices, Inc.
% Stephen Tully, VP, R&D & Technical Operations
Strategic Device Solutions LLC
20 Lawton Lane, Foxborough, MA 02035 USA

Re: K211110
Trade/Device Name: Agile Devices Angler™ Steerable, Deflectable Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: April 14, 2021
Received: April 14, 2021

Dear Stephen Tully:

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,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K211110

Device Name

Agile Devices Angler™ Steerable, Deflectable Microcatheter

Indications for Use *(Describe)*

The Agile Devices Angler™ Steerable, Deflectable Microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the sub-selective region has been accessed, the microcatheter can be used for the controlled infusion of diagnostic agents and delivery of embolic or therapeutic devices. Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.

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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510k SUMMARY

Agile Devices Angler™ Steerable, Deflectable Microcatheter
510(k) K211110

This summary of 510(k) safety and effectiveness information is being submitted per the requirements of 21 CFR 807.92.

A. Submitter: Agile Devices, Inc.
Contact: Stephen Tully
Tel#: (617) 416-5495
Email: stevet99x@gmail.com

B. Manufacturer/ 510(k) Applicant: Agile Devices, Inc.
69 Fox Hill Road
Wellesley, MA 02481
Contact: Stephen Tully
Title: VP, R&D & Technical Operations
Tel #: (617) 416-5495
Email: stevet99x@gmail.com

C. Date Prepared: January 3, 2022

D. Device Name and Classification Information:

Trade Name:	Agile Devices Angler™ Steerable, Deflectable Microcatheter
Common/Usual Name:	Continuous Flush Catheter
Regulation:	21 CFR 870.1210
Product Code:	KRA
Review Panel:	Cardiovascular
Class:	Class II

E. Predicate Device:

Primary: Bend It Technologies, Bendit2.7™ Steerable Microcatheter, (K200582)
Secondary: Merit Medical, SwiftNINJA (K161921)

F. Summary Device Description:

The Agile Devices Angler™ Steerable, Deflectable Microcatheter is a variable stiffness, single lumen microcatheter designed to access small tortuous vasculature. It has a steerable articulating deflectable tip and has a hydrophilic polymer coating over the distal 80cm which gives lubricity when wet. Tip deflection is controlled using a manual steering mechanism / handle external to the body. On-plane bi-directional tip deflection is achieved via coaxial movement of the inner versus the outer shaft which bends a distal covered flat wire. Material injection is achieved via syringe connection to the luer at the proximal end of the catheter.

The Agile Devices Angler™ Steerable, Deflectable microcatheter has a maximum outside diameter of 0.0394" (3F). It has an inside diameter of 0.021" and has two radiopaque marker bands on the distal tip and at the deflection point to facilitate fluoroscopic visualization. It is compatible with guiding catheters with I.D. down to 0.047". The microcatheter lumen is compatible with steerable guidewires up to 0.018", and particles up to 500µm or embolic spheres up to 700µm, with a burst pressure rating up to 1000 psi.

G. Indications for Use Statement:

The Agile Devices Angler™ Steerable, Deflectable Microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the sub-selective region has been accessed, the microcatheter can be used for the controlled infusion of diagnostic agents and delivery of embolic or therapeutic devices. Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.

H. Technical Comparison with Predicate Devices

The table below provides a technological comparison between the Agile Devices Angler™ Steerable, Deflectable Microcatheter and the predicate devices. The similarities and differences between the proposed and predicate devices are discussed following the table.

	Proposed Device Agile Devices Angler™ Steerable, Deflectable Microcatheter	**Primary Predicate Bendit2.7™**	**Reference Predicate SwiftNINJA**
Indications for Use	The Agile Devices Angler™ Steerable, Deflectable Microcatheter is intended for general intravascular use, including peripheral, and coronary vasculature. Once the sub-selective region has been accessed, the microcatheter can be used for the controlled infusion of diagnostic agents and delivery of embolic or therapeutic devices. Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.	The Bendit2.7™ Steerable Microcatheter is intended for general intravascular use, in the peripheral vasculature. The microcatheter can be used for the delivery of diagnostic, embolic, or therapeutic materials into the vasculature. The Bendit2.7 is not intended to be used in intracranial or coronary vessels.	The SwiftNINJA is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vasculature. The catheter should not be used in cerebral vessels.

Catheter type	Steerable, microcatheter	Steerable microcatheter	Steerable microcatheter
Microcatheter Components	Catheter shaft, steerable articulating tip, steerable handle	Catheter shaft, steerable articulating tip, 100° steering handle	Catheter shaft, steerable deflecting tip, steerable handle.
Mode of operation	Catheter insertion and tip placement under imaging guidance. Tip deflection is controlled using a thumb-controlled mechanism external to the body. On-plane bi-directional tip deflection is achieved via coaxial movement of the inner versus the outer shaft which bends a distal covered flat wire Material injection via syringe connection to luer at proximal end of catheter.	Catheter insertion and tip placement under imaging guidance. Tip deflection controlled using manual steering mechanism external to the body. Tip deflection achieved via two NiTi hypo tubes connected at the distal end of catheter with laser-cut patterns that provide tip flexibility. Material injection via syringe connection to luer at proximal end of catheter.	Catheter insertion and tip placement under imaging guidance. Tip articulation controlled using manual steering mechanism externalto the body. Tip articulation achieved via two wires running along the inner walls of the catheter shaft from handle to tip. Material injection via syringe connection to luer at proximal end of catheter.
Catheter OD	3 Fr (0.0394”)	2.7 Fr	2.9 Fr (proximal) / 2.4Fr (distal)
Catheter ID	0.021”	0.021"	0.021”
Catheter shaft length(s)	130 cm and 147 cm	130 cm	125 cm
Hydrophilic coating on shaft	Yes	Yes	Yes
Compatible guidewire	≤ 0.018"	≤ 0.018"	≤ 0.018”
# Lumens	Single	Single	Single
Fill volume	0.4 mL	0.45 mL	0.49 mL

This 510(k) supports the substantial equivalence of the Agile Devices Angler™ Steerable, Deflectable Microcatheter tip deflection mechanism to that of the predicate devices.

The Agile Devices Angler™ Steerable, Deflectable Microcatheter is similar in length to the predicate devices, but also comes in a longer 147 cm length. The Agile Devices Angler™ Steerable Deflectable Microcatheter O.D., I.D., fill volume, and EO sterility method are all similar to the predicate devices.

All devices are single lumen with a hydrophilic coating on the catheter shaft, radiopaque tips, and are intended for single patient use only.

J. Testing to Support Substantial Equivalence

In Vitro Bench Testing

The Agile Devices Angler™ Steerable, Deflectable Microcatheter was tested on bench simulated testing fixtures to demonstrate that the catheter could access arterial and venous vasculature including peripheral and coronary vasculature and to support the substantial equivalence to the Bendit 2.7 Steerable Microcatheter and the SwiftNINJA Microcatheter. Testing was conducted in accordance with ISO 10555-1 Second edition 2013-06-15 Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements (including Amendment 1:2017), where applicable.

1) Visual Inspections and Dimensional verifications
2) Tensile Bond Strength at Tip and Handle Connections
3) Torque Strength (Revolutions to Failure)
4) Radio-Detectability
5) Kink Resistance
6) Liquid Leakage
7) Luer Testing to ISO 80369-7 & ISO 80369-20
8) Tip Flexibility / Softness
9) Tip Deflection Angle and Multiple Deflection Fatigue
10) Resistance to Override
11) Power Injection (for Flowrate and Device Burst Pressure)
12) Coating Tests: Length, Coating Integrity and Particulate
13) Pushability / Trackability and Torque Response

All tests met the pre-defined test acceptance criteria

Shelf Life and Sterility Testing

Agile Devices Angler™ Steerable, Deflectable Microcatheters that had been 2X EtO sterilized and aged in accordance with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices were then subjected to simulated environmental and shipping conditions and tested in accordance with ISTA-2A Simulated Shipping Testing. The product was exposed to environmental

conditioning at cryogenic -20º for 72 hours; tropical 38ºC with 85% RH for 72 hours and then 60 ºC with 30% RH for 6 hours.

Aging was simulated by performing a 6 month Accelerated Aging cycle which was calculated as 26 edays at 50ºC per ASTM F1980:16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Package integrity tests included the dye penetration tests and pouch peel tests per ISO 11607- 1:2019 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems – Part 2: Validation requirements for forming, sealing and assembly processes. Test devices were subjected to integrity testing to confirm proper operation following aging and simulated distribution conditioning. All package and device integrity tests passed.

Sterilization Validation

Ethylene oxide sterilization was validated to a Sterility Assurance Level (SAL) of 10^{-6} using the half-cycle, overkill method per ISO 11135:2014, 2nd edition, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices. Bacterial endotoxin testing conducted using the LAL Test per USP 40-NF35:2017 <85> Bacterial Endotoxins Test confirmed endotoxin levels well below the limit of the standard (< 2.15 EU/Device), Sterilization residuals were evaluated according to ISO 10993-7.

Biocompatibility

The Agile Devices Angler™ Steerable, Deflectable Microcatheter is classified in accordance with ISO 10993-1: 2018, as a Circulating Blood, Externally Communicating device with a Contact Duration of ≤ 24 hours.

The following test were performed to confirm biocompatibility of the patient contacting materials:

- **A.** Cytotoxicity Study Using the ISO Elution Method
- **B.** ISO Guinea Pig Maximization Sensitization Test
- **C.** ISO Intracutaneous Study in Rabbits
- **D.** Acute Systemic Toxicity
- **E.** Material Mediated Pyrogenicity
- **F.** Hemocompatibility
- **G.** SC5b-9 Complement Active Assay
- **H.** ASTM Partial Thromboplastin Time with Sponsor Control
- **I.** In Vivo Thromboresistance Study in Canines – Femoral Artery, Acute

K. Conclusion

The information and testing presented in this 510(k) demonstrate that the Agile Devices Angler™ Steerable, Deflectable Microcatheter is substantially equivalent to the Bendit2.7™ and SwiftNINJA Steerable Microcatheter for the delivery of diagnostic, embolic, or therapeutic materials into the peripheral and coronary vasculature.