Aqure Medical, Inc.
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
Saint Paul, MN 55114

August 6, 2020

Re: K201076
Trade/Device Name: Anchor Dual Lumen Guidewire Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: July 24, 2020
Received: July 27, 2020

Dear Prithul Bom:

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 (Acting)
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)*
K201076

Device Name

Anchor Dual Lumen Guidewire Catheter

Indications for Use *(Describe)*

The Anchor Dual Lumen Guidewire Catheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional devices.

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."

Aqure Medical, Inc.
12560 Fletcher Lane, Suite 300
Rogers, MN 55374 USA
Ph: 763-762-6946

510(k) SUMMARY

Submitter:

Aqure Medical, Inc.
Jie Xia
12560 Fletcher Lane, Suite 300
Rogers, MN 55374
Telephone: 763-762-6946
Email: aquremedical@outlook.com

Primary Contact:

Laurie Lewandowski
Consultant, Honkanen Consulting
738 Saddle Wood Drive
Eagan, MN 55123
Telephone: 612-770-4038 (cell)
Email: lalew207@gmail.com

DATE PREPARED:

August 04, 2020

NAME OF MEDICAL DEVICE:

Proprietary Name: Anchor Dual Lumen Guidewire Catheter
Common/Usual Name: Catheter, Percutaneous

DEVICE CLASSIFICATION:

Classification Name: Percutaneous Catheter
Regulatory Class: II
Product Code: QJP, DQY
Regulation Number: 21 CFR 870.1250

PRIMARY PREDICATE DEVICE:

Proprietary Name: ENVOY® Distal Access (DA) Guiding Catheter
Common/Usual Name: Catheter, Percutaneous
Classification Name: Percutaneous Catheter

510K Number: K140080

PREDICATE DEVICE:

Proprietary Name: MIVI Mi-Axus™ Guide Catheter
Common/Usual Name: Catheter, Percutaneous
Classification Name: Percutaneous Catheter
510K Number: K151396

DEVICE DESCRIPTION:

The Anchor Dual Lumen Guidewire Catheter, model AQ8001, is a single use, sterile (EO), 8F, 110 cm (working length of 100 cm) biocompatible, flexible, radiopaque, dual lumen catheter with a 6F, C shaped tip. The shaft utilizes a braided wire design with multiple Pebax durometer extrusions reflowed over PTFE liner. The distal tip includes radiopaque marker bands for visibility under fluoroscopy. The larger lumen accommodates an 0.035" guidewire and other interventional devices; the smaller lumen allows a 0.014" guidewire to exit the catheter at the curve to provide stabilization of the catheter. The hub, with Luer fittings, is compatible with standard syringes and is leak proof. The hub is marked to identify the lumens.

INTENDED USE/INDICATION FOR USE:

The Anchor Dual Lumen Guidewire Catheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional devices.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

The Anchor Dual Lumen Guidewire Catheter is similar to ENVOY® Distal Access (DA) Guiding Catheter (K140080) and to the MIVI Mi-Axus™ Guide Catheter (K151396) in terms of indications for use, design, materials, technology and performance with the exception that the Anchor Dual Lumen Guidewire Catheter has a second lumen and is not coated whereas the predicates are coated and do not have a second lumen. In addition, the use of contrast is supported by the Asahi Fubuki (K141981).

Characteristic	Aqure Medical, Inc. Anchor Dual Lumen Guidewire Catheter (subject device)	ENVOY® Distal Access (DA) Guiding Catheter (K140080) Primary Predicate	MIVI Mi-Axus™ Guide Catheter (K151396) Predicate Device
Intended Use	To provide intravascular access for patients undergoing intravascular procedures.	Identical	Identical
Indications for use	The Anchor Dual Lumen Guidewire Catheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional devices.	Similar: The ENVOY Distal Access (DA) Guiding Catheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional/diagnostic devices.	Similar; The MIVI Mi-Axus™ Guide Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems.
Technology			
Dimensions	Tip OD = 6F (0.083") Tip ID = 0.067" Catheter OD = 8F (0.105") Large lumen (A) ID ≥ 0.067" Small lumen (B) ID ≥ 0.016"	Catheter OD =6.0F (0.082") ID = 0.071"	Catheter OD= 8F (2.7mm or 0.108") Proximal ID = 6.8F (2.26mm or 0.089") Lengths (cm)= 75 ± .5 or 85

Characteristic	Aqure Medical, Inc. Anchor Dual Lumen Guidewire Catheter (subject device)	ENVOY® Distal Access (DA) Guiding Catheter (K140080) Primary Predicate	MIVI Mi-Axus™ Guide Catheter (K151396) Predicate Device
	Working Length (cm) = 100	Working Lengths (cm) =95 and 105	± .5
Curve Shape	C	Identical	Not Listed
Tip	Atraumatic with marker bands	Identical	Identical
Shaft	Braided and coiled shaft with multiple Pebax durometer extrusions reflowed over PTFE liner	Identical	Identical
Coating	N/A	Hydrophilic	Hydrophilic
Packaging	Card mounted inserted in a sterile barrier pouch and shelf box	Identical	Not Listed
Sterilization	Ethylene Oxide	Identical	Identical

The Anchor Dual Lumen Guidewire Catheter is the same as the primary predicate ENVOY® Distal Access (DA) Guiding Catheter (K140080) with the addition of the second lumen, that terminates at the curve, to provide stability. The physician can introduce interventional devices or contrast per current practice. The catheter tip French size remains consistent with the predicate at 6 F, while the remaining portion of the shaft increase to 8F to accommodate the second lumen. This is supported by the 8F, MIVI Mi-Axus Guide Catheter (K151396) predicate. Contrast use with the subject device is supported by the reference device, the Asahi Fubuki (K141981).

The length of the Anchor Dual Lumen Guidewire Catheter falls within the two lengths provided by the predicate. The subject device is not coated while the predicate devices have a hydrophilic coating. Testing demonstrated that the subject device can be inserted into the simulated

model in an equivalent manner to the predicate device and that typical treatment devices can be inserted and withdrawn to meet specifications.

The different technological characteristics of the new device do not raise different questions of safety and effectiveness.

PERFORMANC TESTING

The Anchor Dual Lumen Guidewire Catheter has been tested and verified that the catheter performs as designed and is suitable for its intended use.

Performance testing included the following:

Test	Test Method Summary	Results
Visual Inspection	Visually inspect device 2.5x magnification per ISO 10555-1.	All devices met the acceptance criteria and were smooth with no nicks or sharp edges.
Dimensions	The working and usable lengths, ID of both lumens, the catheter and tip ODs, curve tip length and curve angle were measured.	Devices met their specifications.
System Surface, Atraumatic Tip and Lumen Transition	Inspect at 2.5x magnification per ISO 10555-1	Devices met their specifications. Surface was free from extraneous matter and sharp edges, catheter tips and distal openings point or sharp edges,
Proximal Hub Compatibility	Inspect to ISO 80369-7 dimensions (using gages) after conditioning in distilled water	Devices met acceptance criteria
Buckle	Distal tip buckling force under compressive load was evaluated	Devices met their specifications
Flexibility and Kink	Observation for kink when wrapped around a decreasing mandrel	Devices met their specifications
Torque	With the distal end fixed within the model, torque until failure.	Devices met their specifications
Liquid Leakage	Leak test per ISO 10555-2	Device met acceptance criteria
Air Leakage	Leak test per ISO 10555-1, Annex D	Device met acceptance criteria
Contrast Flow Rate	Connect a syringe filled with a min of 25ml Visipaque to large lumen. Inject over 5 seconds; measure amount of contrast collected.	Devices met acceptance criteria
Tensile Strength	Tensile test all joints per ISO 10555-1.	Devices met accept criteria.
Particulate	Testing per ISO14708-1:2014 & EN45502-1:2015	Devices met accept criteria
• Functionality • Stabilization	Subject and predicate devices were tested in a	All devices met the acceptance criteria. The Anchor Dual Lumen Guidewire Catheter

Test	Test Method Summary	Results
• Guidewire compatibility • ID obstruction / delamination	simulated use model for functionality, retropulsion and liner obstruction / delamination	demonstrated 78% less retropulsion than the predicate. No obstruction or delamination was observed
Physician Simulated Use	Subject and predicate devices were used by two physicians in a simulated use model. This included small and large lumen compatibility with guidewires and treatment devices.	Physicians deemed the performance of the subject device acceptable and experienced significantly less retropulsion than the predicate. Five (5) predicate devices backed out of position and one (1) predicate kinked. The Anchor Dual Lumen Guidewire Catheter was compatible with the size labeled guidewires and treatment devices.
Shelf Life Testing	Devices were subjected to all testing post 6 month accelerated aging per ASTM F1980:2016.	All devices met the acceptance criteria post accelerated aging.
Packaging		
Packaging Testing	Distribution, Environmental and Aging of Packages • Distribution Testing per ISTA 2A:2011 • Packaging Tests per ASTM D4169:2016 and ISO 11607-1:2006 • Packaging Aging per ASTM F1980:2016, o Visual per ASTM F1886-16 o Dye Leak per ASTM F2096-11 o Seal Strength per ASTM F88/F88M-15	Packages met specifications (subject devices met accept criteria as described above) post Distribution, Environmental and Aging of Packages
Biocompatibility		
Cytotoxicity	MEM Extraction Cytotoxicity Assay per ISO 10993-5:2009	Non-cytotoxic
Sensitization	Guinea Pig Maximization Test per ISO 10993-10:2010	Non-sensitizing
Irritation	Intracutaneous Reactivity Test per ISO 10993-10:2010	Non-irritant
Toxicity	Materials Mediated Rabbit Pyrogen Test ISO 10993-11:2017	Non-pyrogenic

Test	Test Method Summary	Results
Toxicity	Acute Systemic Toxicity per ISO 10993-11:2017	Non-toxic
Hemocompatibility	ASTM Hemolysis Assay: Direct and Extract Methods per ISO 10993-4:2017	Non-hemolytic
Hemocompatibility	Complement Activation Assay – C3a and SC5b-9 Methods per ISO 10993-4:2017	C3a and SC5b-9 complement proteins were considered to be non-activated as compared to the negative control
Hemocompatibility	Partial Thromboplastin Time (PTT) Assay per ISO 10993-4:2017	The expanded assay and comparison article: Pass (the test article's p-value was ≥ 0.05 when compared to the negative plasma control or negative reference control)
Hemocompatibility	4-Hour Thrombogenicity Study in Canine per ISO 10993-4:2017	Equivalent thromboresistant characteristics as the predicate.

CONCLUSIONS

The Anchor Dual Lumen Guidewire Catheter is substantially equivalent in design, materials, sterilization, principles of operation, performance and indications for use to the cited predicate devices.