DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 18, 2017

Sequent Medical, Inc.
Bethany Barrett
Regulatory/Clinical Project Manager
11A Columbia
Aliso Viejo, California 92656

Re: K162565
Trade/Device Name: VIA™ 17 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: January 26, 2017
Received: February 1, 2017

Dear Ms. Barrett:

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,

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): K162565*

Device Name
VIA™ 17 Microcatheter

Indications for Use *(Describe)*
The VIA™ 17 Microcatheter is intended for the introduction of non-liquid interventional devices (such as coils/ stents) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral and coronary vasculature.

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

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

DATE PREPARED	2/17/2017
APPLICANT	Sequent Medical, Inc. 11A Columbia Aliso Viejo, CA 92656 Tel: (949) 830-9600 Fax: (949) 830-9658
OFFICIAL CORRESPONDENT	Bethany Barrett 11A Columbia Aliso Viejo, CA 92656 bethanyb@sequentmedical.com Tel: (949) 830-9600 x 113 Fax: (949) 830-9568
TRADE NAME	VIA™ 17 Microcatheter
COMMON NAME	Percutaneous Catheter, Continuous Flush Catheter
DEVICE CLASSIFICATION	Class II, 21 CFR §870.1250, §870.1210
PRODUCT CODES	DQY: Percutaneous Catheter KRA: Continuous Flush Catheter
PREDICATE DEVICES	VIA™ 21 Microcatheter (K150894) VIA™ and VIA™ PLUS Microcatheters (K132652) Headway 17 Advanced Microcatheter (K101542)

SUBSTANTIALLY EQUIVALENT TO:

The VIA™ 17 Microcatheter is substantially equivalent to the previously cleared VIA 21 Microcatheter (K150894), VIA (VIA 27) and VIA PLUS (VIA 33) Microcatheters (K132652), and Headway 17 Advanced Microcatheter (K101542).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The VIA™ 17 Microcatheter is a sterile single lumen device designed to aid the physician in accessing distal vasculature when used with a guide catheter and steerable guidewire. Variable shaft stiffness ranging from a flexible tip to a semi-rigid proximal section aid the physician in tracking over selectively placed guidewires. The proximal end of the catheter incorporates a standard luer adapter to facilitate attachment of accessories. A single radiopaque marker positioned at the distal tip facilitates fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic

coating which reduces friction during manipulation in the vessel. The inner lumen of the catheter has a PTFE liner which assists with delivery of interventional devices, such as coils/stents.

The VIA™ 17 Microcatheter is available in an effective length of 154 cm and an inner diameter of 0.0175 inches.

The VIA™ 17 Microcatheter is presented in a tyvek pouch and is sterile, single use only and non-pyrogenic.

Accessories: Each VIA™ 17 Microcatheter is provided with shaping mandrels to facilitate distal tip shaping.

In intravascular procedures, the device assists the physician in:

- Accessing the targeted vasculature to facilitate the delivery of interventional devices, such as coils and stents, and infusion of diagnostic agents such as contrast.

INDICATIONS FOR USE:

The VIA™ 17 Microcatheter is intended for the introduction of non-liquid interventional devices (such as coils/stents) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral and coronary vasculature.

TECHNICAL CHARACTERISTICS:

The VIA™ 17 Microcatheter incorporates variable shaft stiffness ranging from a flexible tip to a semi-rigid proximal section aid the physician in tracking over selectively placed guidewires. The inner lumen incorporates a PTFE liner to facilitate movement of devices through the catheter's lumen to the intended destination in the vasculature. The outer surface of the catheter is coated with a hydrophilic coating which reduces friction during manipulation in the vessel. The tip of the catheter can be steam shaped by physician for proper adjustment to the anatomy prior to use.

PERFORMANCE DATA:

Device performance testing confirms that the VIA™ 17 Microcatheter can be used according to its intended use. The VIA™ 17 Microcatheter has been verified and validated according to Sequent Medical's procedures for product design and development. Performance testing included:

- Bench Testing
- Sterilization Validation
- Packaging and Shelf Life Assessment
- Biocompatibility Assessment
- Simulated Use Testing in Animals

This testing regime demonstrates that the subject device is substantially equivalent to the legally marketed predicate device, for its intended use in the introduction of interventional devices and infusion of diagnostic agents into the vasculature.

The information provided by Sequent Medical in this 510(k) application was found to be substantially equivalent to the predicate devices, the VIA 21 Microcatheter (K150894), VIA (VIA 27) and VIA PLUS (VIA 33) Microcatheters (K132652), and the Headway 17 Advanced Microcatheter (K101542).

NONCLINICAL TESTS DISCUSSION:

The nonclinical tests included:

- Physical characteristics unique to the VIA™ 17 Microcatheter, such as visual and dimensional tolerances, kink resistance, and catheter tip shape retention.
- Safety features such as burst pressure, tensile force and coating adherence.
- Functional characteristics such as navigation and track force. Interventional device retraction and catheter flow rate.
- The full list of non-clinical tests are listed in Table 1 below:

Table 1. Non-Clinical Tests

Test	Test Method Summary	Result
Kink Resistance	This method measures the diameter at which the VIA shaft sections and junctions will kink. Each catheter section is inserted into an automated test fixture and kinked. The kink diameter is then calculated based on shaft displacement at peak force.	All units passed acceptance criteria. Acceptance criteria based on measured Headway 17 kink resistance. Substantially equivalent to predicate.
Tip Buckling	This method measures the catheter tip buckling force by pushing the catheter tip into a load cell until it buckles. The peak force is measured and recorded.	All units passed acceptance criteria. Acceptance criteria based on measured Headway 17 tip buckling. Substantially equivalent to predicate.
Tracking Force	This method tests the force required to pass interventional devices through the VIA catheter. Each VIA is inserted into a tracking fixture and the hard model tortuosity fixture. The interventional device is pushed through the tortuosity fixture and VIA catheter. The peak force required to push the device through the VIA is recorded.	All units passed acceptance criteria. Acceptance criteria identical to VIA 21 and VIA 27/33. Substantially equivalent to predicate.

Test	Test Method Summary	Result
Steam Shaping and Shape Retention	This method measures the ability of the VIA to be steam shaped using a shaping mandrel and the ability of the VIA to hold the shape during use. The VIA is shaped per the VIA IFU shaping instructions. The tip angle is measured and must fall within the documented specification. The VIA is then subjected to simulated use through a guide catheter in 37° water. After guidewire insertion for a specified time, the tip angle is measured again and shape retention is evaluated per the specification.	All units passed acceptance criteria. Acceptance criteria based on measured Headway 17 shape retention. Substantially equivalent to predicate.
Microcatheter Tensile Strength	This method tests the tensile strength of the microcatheter shaft sections (each joint/transition tested individually). This method aligns with the method described in ISO 10555-1:2014.	All units passed acceptance criteria per ISO10555-1:2014. Substantially equivalent to predicate.
Catheter Leakage and Static Burst	This method measures the leakage and static burst pressure of the VIA. This method aligns with the method described in ISO 10555-1:2014.	All units passed acceptance criteria. Acceptance criteria identical to VIA 21 and VIA 27/33. Substantially equivalent to predicate.
Retraction	This method measures the distance that the VIA catheter pulls back during interventional device recapture. This test is performed in a simulated use model. The guide catheter and VIA Microcatheter are inserted into the fixture. A worst case interventional device is deployed through the VIA and recaptured. The displacement of the catheter in the fixture is measured and recorded.	All units passed acceptance criteria. Acceptance criteria identical to VIA 21 and VIA 27/33. Substantially equivalent to predicate.
Coating Friction and Coating Integrity	Measures the catheter coating friction/lubricity over multiple friction test cycles using an automated friction tester. Coating integrity uses dye to test that coating remains adhered to catheter after simulated use through a tortuous model.	All units passed acceptance criteria. Acceptance criteria identical to VIA 21 and VIA27/33. Substantially equivalent to predicate.
Coating Adherence/ Particulate	This method measures the particulate generated during simulated navigation and adjunct device delivery. The VIA is cycled through the tracking fixture and the hard model tortuosity fixture. A worst case interventional device is then cycled through the inner diameter (ID) of the VIA while inside the tortuosity fixture. Both the ID of the fixture and the ID of the VIA are flushed with particulate free water and the collected fluid is tested for particulate using the light obscuration method.	All units passed acceptance criteria per USP24 <788>. Acceptance criteria identical to VIA 21 and VIA27/33. Substantially equivalent to predicate.
Flow Rate	This method measures the flow rate through the VIA by pushing fluid through the catheter at a constant rate while pressure is being monitored.	All units passed acceptance criteria per ISO10555-1:2014. Flow rate was

Test	Test Method Summary	Result
		determined and documented in the instructions for use. Substantially equivalent to predicate.
Hub Performance	This method tests hub liquid and air leakage, as well as that the hub can withstand adequate forces. Tests that the hub meets general requirements for conical fittings. Methods used are per ISO594-1:1986 and ISO 594-2:1998.	Test results adopted from VIA 27/VIA33 (K132652). All units passed acceptance criteria per ISO594-1:1986 and ISO 594-2:1998. Substantially equivalent to predicate.
Visual and Dimensional	This method measures inner diameter, outer diameter, catheter length, coated length, tip length, distance between marker bands, and unbraided length.	All units passed acceptance criteria. Substantially equivalent to predicate.
Catheter Torque to Failure	This method measures how many complete rotations the catheter can withstand before breaking. The catheter is inserted through a tortuous model inside a heated water bath. The distal end of the catheter is secured in place and the proximal end is rotated until failure. This test is performed in both clockwise and counterclockwise directions.	Characterization only. Results comparable to VIA 21. Substantially equivalent to predicate.

Nonclinical testing demonstrated that the VIA™ 17 Microcatheter can perform as intended, and demonstrated substantial equivalence to the predicate devices: VIA 21 Microcatheter (K150894), VIA (VIA 27) and VIA PLUS (VIA 33) Microcatheters (K132652), and Headway 17 Advanced Microcatheter (K101542).

BIOCOMPATIBILITY AND CHEMICAL TESTING:

Biocompatibility and chemical testing was adopted from the testing performed on the VIA (VIA 27) Microcatheter. The full list of biocompatibility and chemical testing that was adopted can be found in Table 2 below:

Table 2. Biocompatibility and Chemical Testing

Biocompatibility Testing		
Test	**Applicable International Standard**	**Result**
Materials Mediated Rabbit Pyrogen Test	ISO10993-11:2006	Non-pyrogenic - **Pass**
ISO Guinea Pig Maximization Sensitization	ASTM F720-81 (2002)	Non-sensitization response - **Pass**

Test	Applicable International Standard	Result
ISO Acute Systemic Injection Test	ISO10993-11:2006	Non Toxic - **Pass**
ISO Intracutaneous Reactivity Test	ISO10993-10:2010	Non-irritant - **Pass**
Four Hour Thromboresistance Evaluation in Dogs	ISO10993-4:2002 (2006)	Thromboresistance characteristics of test group similar to control – **Pass**
ASTM Hemolysis Assay Direct Contact and Extract	ISO10993-4:2002 (2006) ASTM F619-03 ASTM F756-08	Non-hemolytic under direct and extract test conditions - **Pass**
Complement Activation with Comparison Article	ISO10993-4:2002 (2006)	Results of test group comparable to control group – **Pass**
Partial Thromboplastin Time with Comparison Article	ISO10993-4:2002 (2006) ASTM F2382-04	Results of test group comparable to control group –both non-activators of the intrinsic coagulation pathway – **Pass**
Platelet and Leukocyte Counts with Comparison Article	ISO10993-4:2002 (2006)	Results of test group comparable to control group – **Pass**
ISO MEM Elution Assay with L-929 Mouse Fibroblast	ISO10993-5:2009	Non-toxic – **Pass**
Chemical Testing		
Test	**Applicable International Standard**	**Result**
Colorant Analysis Testing	21 CFR 74.3045 (2012)	Elemental results meet requirements of 21 CFR 74.3045 - **Pass**

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

A technological comparison, as well as bench and simulated use testing demonstrate the substantial equivalence of the VIA™ 17 Microcatheter to the predicate devices. Table 3 below shows a summary of the VIA™ 17 technological characteristics as compared to the predicate devices.

Table 3. Substantial Equivalence Summary – Technological Characteristics

Element	SUBJECT DEVICE - VIA™ 17 MICROCATHETER	VIA™ 21 MICROCATHETER (K150894)	VIA™ (VIA 27) AND VIA™ PLUS (VIA 33) MICROCATHETER (K132652)	HEADWAY 17 ADVANCED MICROCATHETER (K101542)
Summary of Differences in Technological Characteristics				
The subject and predicate devices are substantially equivalent with respect to design characteristics. The slight variations in flexibility as well as differences in ID and OD are what differentiate these catheters. Each manufacturer optimizes these design variations towards a more specific application (e.g. infusion of diagnostic and therapeutic agents) or for the introduction of specific devices such as embolic agents, coils and stents. Devices are composed of similar materials, all of which have extensive clinical history of safe use in medical devices				
Design Features – Equivalent ?				
Materials	PTFE, Pebax, Vestamid, Stainless Steel wire, Polypropylene **Yes**	PTFE, Pebax, Vestamid, Stainless Steel wire, Polypropylene **Yes**	PTFE, Pebax, Vestamid, Stainless Steel wire, Polypropylene **Yes**	PTFE, Pebax, Stainless Steel wire, Nylon Santoprene **Yes**
Tip Shape	Straight tip configuration and the physician has the option to steam shape the tip using the Shaping Mandrel prior to use to ensure proper adjustment to the anatomy. **Yes**	Straight tip configuration and the physician has the option to steam shape the tip using the Shaping Mandrel prior to use to ensure proper adjustment to the anatomy. **Yes**	Straight tip configuration and the physician has the option to steam shape the tip using the Shaping Mandrel prior to use to ensure proper adjustment to the anatomy. **Yes**	Straight tip configuration and the physician has the option to steam shape the tip prior to use to ensure proper adjustment to the anatomy. **Yes**

Element	SUBJECT DEVICE - VIA™ 17 MICROCATHETER	VIA™ 21 MICROCATHETER (K150894)	VIA™ (VIA 27) AND VIA™ PLUS (VIA 33) MICROCATHETER (K132652)	HEADWAY 17 ADVANCED MICROCATHETER (K101542)
Effective Lengths	Via 17: 154 cm **Yes**	Via 21: 154 cm **Yes**	Via 27: 154 cm Via 33: 133 cm **Yes**	150 cm **Yes**
Proximal/Distal OD	Via 17: Proximal 2.5F/Distal 2.2F **Yes**	Via 21: Proximal 2.8F/Distal 2.5F **Yes**	Via 27: Proximal 3.2F/Distal 3.0F Via 33: Proximal 3.8 F/Distal 3.4F **Yes**	Proximal OD: 2.4F Distal OD: 1.7F **Yes**
ID	Via 17: 0.0175 inch/ 1.3F **Yes**	Via 21: 0.021 inch/ 1.6F **Yes**	Via 27: 0.027 inch/ 2.1F Via 33: 0.033 inch/2.5F **Yes**	ID: 0.017 inch **Yes**
Hydrophilic Coating Length	Via 17: 100 cm **Yes**	Via 21: 100 cm **Yes**	Via 27: 100 cm Via 33: 100 cm **Yes**	102 cm (measured) **Yes**
Tip Length	1mm **Yes**	1mm **Yes**	1mm **Yes**	0.64 mm (measured) **Yes**
Distal Tip Length	Via 17: 10cm **Yes**	Via 21: 5cm **Yes**	Via 27:10cm Via 33: 5 cm **Yes**	11cm **Yes**

Element	SUBJECT DEVICE - VIA™ 17 MICROCATHETER	VIA™ 21 MICROCATHETER (K150894)	VIA™ (VIA 27) AND VIA™ PLUS (VIA 33) MICROCATHETER (K132652)	HEADWAY 17 ADVANCED MICROCATHETER (K101542)
Tip Markers	2 markers, 90%Pt-10%Ir **Yes**	1 marker, 90%Pt-10%Ir **Yes**	1 marker, 90%Pt-10%Ir **Yes**	2 markers, confirmed to be radiopaque **Yes**
Coating	Polyvinylpyrrolidone **Yes**	Polyvinylpyrrolidone **Yes**	Polyvinylpyrrolidone **Yes**	Confirmed to be lubricious **Yes**
Method of supply	Sterile, single-use, non-pyrogenic **Yes**	Sterile, single-use, non-pyrogenic **Yes**	Sterile, single-use, non-pyrogenic **Yes**	Sterile, single-use, non-pyrogenic **Yes**
Packaging	Primary package: Coiled Hoop within a single pouch Secondary Package: Chipboard unit carton **Yes**	Primary package: Coiled Hoop within a single pouch Secondary Package: Chipboard unit carton **Yes**	Primary package: Coiled Hoop within a single pouch Secondary Package: Chipboard unit carton **Yes**	Primary package: Coiled Hoop within a single pouch Secondary Package: Chipboard unit carton **Yes**
Sterilization	Ethylene Oxide Sterilization **Yes**	Ethylene Oxide Sterilization **Yes**	Ethylene Oxide Sterilization **Yes**	Ethylene Oxide Sterilization **Yes**

Element	SUBJECT DEVICE - VIA™ 17 MICROCATHETER	VIA™ 21 MICROCATHETER (K150894)	VIA™ (VIA 27) AND VIA™ PLUS (VIA 33) MICROCATHETER (K132652)	HEADWAY 17 ADVANCED MICROCATHETER (K101542)
Indication for Use – Equivalent ?				
The Subject and the comparison devices maintain similar indications	The VIA 17 Microcatheter is intended for the introduction of non-liquid interventional devices (such as coils/stents) and infusion of diagnostic agents (such as contrast media) into the neuro, peripheral, and coronary vasculature. **Yes**	The VIA Catheter is intended for the introduction of non-liquid interventional devices (such as stents/flow diverters) and infusion of diagnostic (such as contrast media) or non-liquid therapeutic agents into the neuro, peripheral, and coronary vasculature. **Yes**	The VIA Catheter is intended for the introduction of non-liquid interventional devices (such as stents/flow diverters) and infusion of diagnostic (such as contrast media) or therapeutic agents into the neuro, peripheral, and coronary vasculature. **Yes**	The Headway 21 Microcatheter is intended to for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils. **Yes**
Summary Statement of Substantial Equivalence				
Use in a clinical setting was conducted in animals to show that no new risks were identified and that the safety and effectiveness profile is similar to well-established comparison market-approved devices. Bench Testing was performed in models representing the higher risk neurovascular anatomy, which is the worst case representation of the cardiac and peripheral vascular anatomies. The VIA™ 17 Microcatheter has equivalent performance characteristics to the comparison devices.				