DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 28, 2015

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

Re: K150894
Trade/Device Name: VIA™ 21 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: July 27, 2015
Received: July 29, 2015

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 yours,

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)*
K150894

Device Name
VIA™ 21 Microcatheter

Indications for Use *(Describe)*

The VIA™ 21 Microcatheter 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.

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	4/1/2015
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™ 21 Microcatheter
COMMON NAME	Continuous Flush Catheter
DEVICE CLASSIFICATION	Class II, 21 CFR §870.1250, 21 CFR §870.1210
PRODUCT CODES	DQY: Percutaneous Catheter KRA: Continuous Flush Catheter
PREDICATE DEVICES	VIA™ (VIA 27) and VIA™ PLUS (VIA 33) Microcatheters (K132652) Headway 21 Microcatheter (K093160) Orion Microcatheter (K113289)
PRIOR SUBMISSION	This is an original submission. There has been no prior submission for the subject device.

SUBSTANTIALLY EQUIVALENT TO:

The VIA™ 21 Microcatheter is substantially equivalent to the previously cleared VIA™ (VIA 27) and VIA™ PLUS (VIA 33) Microcatheters (K132652), Headway 21 Microcatheter (K093160) and Orion Microcatheter (K113289).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The VIA™ 21 Microcatheter is designed to be introduced over a steerable guidewire into the vasculature. The physician inserts the catheter into the vein or artery through the skin (percutaneous) using a sheath or guidewire. The device can then be navigated to the treatment site. Navigation is aided by the coated surface of the catheter which assists with

manipulation while in the vasculature. Throughout the procedure the physician can obtain the position of the catheter by the tip marker using fluoroscopic techniques. Diagnostic, therapeutic and interventional devices can be delivered through the lumen of the catheter to the treatment site.

The VIA™ 21 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 an intraluminal flow diverter.

The VIA™ 21 Microcatheter is available in an effective length of 154 cm and an inner diameter of 0.021 inches.

The VIA™ 21 Microcatheter is presented in a tyvek pouch and is sterile, single use only and non-pyrogenic.

Accessories: Each VIA™ 21 Microcatheter is provided with a shaping mandrel 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 intraluminal flow diverters, infusion of diagnostic agents such as contrast and infusion of therapeutic agents.

INDICATIONS FOR USE:

The VIA™ 21 Microcatheter 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.

TECHNICAL CHARACTERISTICS:

The VIA™ 21 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™ 21 Microcatheter can be used according to its intended use. The VIA™ 21 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, infusion of diagnostic and non-liquid therapeutic 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, VIA™ (VIA 27) and VIA™ PLUS (VIA 33) Microcatheters (K132652), Headway 21 Microcatheter (K093160) and Orion Microcatheter (K113289).

NONCLINICAL TESTS DISCUSSION:

The nonclinical tests included:

- Physical characteristics unique to the VIA™ 21 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	Methodology	Applicable International Standard and/or Sequent Test Method (TM)	Result	Conclusion
Visual and Dimensional	Tests conformance to specified microcatheter dimensions and visual criteria.	ISO 10555-1:2013 TM036	Met performance specifications per DTM003	Complete conformance to standard

Test	Methodology	Applicable International Standard and/or Sequent Test Method (TM)	Result	Conclusion
Kink Resistance	Measures diameter at which microcatheter shaft sections and junctions will kink.	BS EN 13868:2002 TM035	Met performance specifications per DTM003	Conformance to standard with the following deviations: Kink diameter determined based on mechanical kink (drop in compressive force) instead of 50% reduction in water flow. This method is appropriate as the Via 21 is primarily used to deliver non-liquid devices.
Tip Buckling	Tests force required for tip to buckle.	TM034	Met performance specifications per DTM003	Complete conformance to Sequent TM
Tracking Force	Tests force required to advance an interventional device through the microcatheter lumen.	TM032	Met performance specifications per DTM003	Complete conformance to Sequent TM
Steam Shaping and Shape Retention	Tests that microcatheter can be steam shaped to a clinically relevant angle and can maintain a minimum % of the initial angle after simulated use.	TM038	Met performance specifications per DTM003	Complete conformance to Sequent TM
Shaft Tensile	Measures the ultimate tensile strength of all Pebax and Vestamid junctions along the length of the catheter shaft.	ISO 10555-1:2013 TM031	Met performance specifications per DTM003	Complete conformance to standard
Hub-Shaft Tensile	Measures the ultimate tensile strength of the hub to shaft junction.	ISO 10555-1:2013 TM031	Met performance specifications per DTM003	Complete conformance to standard
Burst	Measures peak pressure before microcatheter burst/liquid leakage.	ISO 10555-1:2013 TM037	Met performance specifications per DTM003	Complete conformance to standard

Test	Methodology	Applicable International Standard and/or Sequent Test Method (TM)	Result	Conclusion
Coating Friction and Coating Integrity	Measures the average peak coating friction/lubricity. Coating integrity uses dye to test that coating remains adhered to catheter after simulated use.	Harland Medical Systems Coating Friction and Dye Test Methods FDA Guidance Document, Class II Special Controls for PTCA Catheters (section 12) (Issued 2010)	Met performance specifications per DTM003	Complete conformance to Harland test methods In line with FDA guidance document on coating integrity
Coating Adherence/Particulate	Measures particulate generated from the hydrophilic coating on exterior of microcatheter, as well as particulate generated from advancing an interventional device through the inner lumen of the microcatheter.	TM042 FDA Guidance Document, Non-Clinical Engineering Tests for Intravascular Stents and Associated Delivery Systems (section 12) (Issued 2010) FDA Guidance Document, Class II Special Controls for PTCA Catheters (section 13) (Issued 2010)	Met performance specifications per DTM003	Complete conformance to Sequent TM In line with FDA guidance documents on particulate testing
Flow Rate	Measures flow rates through the microcatheter at defined injection rates using saline and contrast.	ISO 10555-1:2013	Met performance specifications per DTM003	Complete conformance to standard
Hub Performance	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.	ISO 594-1:1986 ISO 594-2:1998 TM043	Test results adopted from VIA 27/VIA33 (K132652)	Conformance to standard with the following deviations: Used an alternative ISO 594-2:1998 fitting to test hubs for Separation Force and Unscrewing Torque. The fitting used was measured to have a minor diameter greater than called for in

				the standard. This was deemed as worst case for these tests, therefore acceptable to use. Only short term stress cracking was inspected for on hubs. ISO 594-2:1998 calls for inspection after 48 hours. Intended use of Via 21 microcatheter only requires RHV or syringes to be connected for short durations during delivery of implant, therefore long term testing is not applicable.

Nonclinical testing demonstrated that the VIA™ 21 Microcatheter can perform as intended, and demonstrated substantial equivalence to the predicate devices: VIA™ (VIA 27) and VIA™ PLUS (VIA 33) Microcatheters (K132652), Headway 21 Microcatheter (K093160) and Orion Microcatheter (K113289).

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**
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™ 21 Microcatheter to the predicate devices. Table 3 below shows a summary of the VIA™ 21 technological characteristics as compared to the predicate devices.

Table 3. Substantial Equivalence Summary – Technological Characteristics

Element	SUBJECT DEVICE - VIA™ 21 MICROCATHETER (K150894)	VIA™ (VIA 27) AND VIA™ PLUS (VIA 33) MICROCATHETER (K132652)	HEADWAY 21 MICROCATHETER (K093160)	ORION ™ MICROCATHETER CATHETER (K113289) AND CE0297)
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, Stainless Steel wire, Nylon Santoprene **Yes**	PTFE, Pebax, Stainless Steel hypotube, Nitinol braid reinforcement, polypropylene **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 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™ 21 MICROCATHETER (K150894)	VIA™ (VIA 27) AND VIA™ PLUS (VIA 33) MICROCATHETER (K132652)	HEADWAY 21 MICROCATHETER (K093160)	ORION ™ MICROCATHETER CATHETER (K113289) AND CE0297)
Effective Lengths	Via 21: 154 cm **Yes**	Via 27: 154 cm Via 33: 133 cm **Yes**	150 cm **Yes**	150 cm **Yes**
Proximal/Distal OD	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: 2.5F Distal OD: 2.0F **Yes**	Proximal OD: 2.4F Distal OD: 2.6F **Yes**
ID	Via 21: 0.021 inch/ 1.6F **Yes**	Via 27: 0.027 inch/ 2.1F Via 33: 0.033 inch/2.5F **Yes**	ID: 0.021 inch **Yes**	ID: 0.021 inch **Yes**
Hydrophilic Coating Length	Via 21: 100 cm **Yes**	Via 27: 100 cm Via 33: 100 cm **Yes**	100cm (measured) **Yes**	85 cm (measured) **Yes**
Tip Length	1mm **Yes**	1mm **Yes**	0.66 mm (measured) **Yes**	0.70 mm (measured) **Yes**

Element	SUBJECT DEVICE - VIA™ 21 MICROCATHETER (K150894)	VIA™ (VIA 27) AND VIA™ PLUS (VIA 33) MICROCATHETER (K132652)	HEADWAY 21 MICROCATHETER (K093160)	ORION ™ MICROCATHETER CATHETER (K113289) AND CE0297)
Distal Tip Length	Via 21: 5cm **Yes**	Via 27:10cm Via 33: 5 cm **Yes**	15cm (measured) **Yes**	13.5 cm (measured) **Yes**
Tip Markers	1 marker, 90%Pt-10%Ir **Yes**	1 marker, 90%Pt-10%Ir **Yes**	2 markers, confirmed to be radiopaque **Yes**	2 markers, confirmed to be radiopaque **Yes**
Coating	Polyvinylpyrrolidone **Yes**	Polyvinylpyrrolidone **Yes**	Confirmed to be lubricious **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	Ethylene Oxide Sterilization **Yes**	Ethylene Oxide Sterilization	Ethylene Oxide sterilization

Element	SUBJECT DEVICE - VIA™ 21 MICROCATHETER (K150894)	VIA™ (VIA 27) AND VIA™ PLUS (VIA 33) MICROCATHETER (K132652)	HEADWAY 21 MICROCATHETER (K093160)	ORION ™ MICROCATHETER CATHETER (K113289) AND CE0297)
	Yes		**Yes**	**Yes**
Indication for Use – Equivalent ?				
The Subject and the comparison devices maintain similar indications	The VIA 21 Microcatheter 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 (K093160) 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**	The Orion™ Catheter (K113289 and CE0297) is intended for the controlled selective infusion of physician-specified therapeutics agents or contrast media into the vasculature of the peripheral and neuro anatomy. **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™ 21 Microcatheter has equivalent performance characteristics to the comparison devices.				