August 6, 2020

Merit Medical Systems, Inc.
Michaela Rivkowich
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K201907
Trade/Device Name: ClariVein IC
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: July 8, 2020
Received: July 9, 2020

Dear Ms. Rivkowich:

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,

For

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201907

Device Name
ClariVein IC

Indications for Use *(Describe)*
The ClariVein IC is indicated for the infusion of physician-specified agents in the peripheral vasculature (e.g., superficial veins, saphenous veins).

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: K201907

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 316-3632
	Contact Person:	Michaela Rivkowich
	Date Prepared:	07/08/2020
	Registration Number:	1721504
Subject Device	Trade Name:	ClariVein® IC
	Common/Usual Name:	Intravascular Catheter, Infusion Catheter, Cannula
	Classification Name:	Continuous Flush Catheter
	Premarket Notification:	K201907
	Regulatory Class:	Class II
	Product Code:	KRA
	21 CFR §:	870.1210
	Review Panel:	Cardiovascular
Predicate Device	Trade Name:	ClariVein® IC
	Classification Name:	Continuous Flush Catheter
	Premarket Notification:	K153502
	Manufacturer:	Merit Medical Systems, Inc.
	This predicate has not been subject to a design-related recall.	
Reference Device	No reference devices were used in this submission.	

Device Description	The ClariVein IC is a specialty infusion catheter available in multiple lengths (45cm, 65cm, 85cm). The catheter assembly, including the catheter shaft, infusion port, and rotatable wire, is connected by means of a cartridge to an integral self-contained motor drive unit (MDU). The MDU includes the syringe support, handle grip, wire rotation speed selectors, and trigger features for physician-controlled infusion of a physician-specified agent. The .035" (2.7F) outside diameter of the ClariVein IC catheter is compatible with an 18 gauge or greater short peripheral catheter or a 4Fr or greater introducer to gain vascular access. The ClariVein IC is labeled sterile for single use and is provided with instruction for its safe and effective use. It has no serviceable or reusable parts. It is entirely disposable post procedure. The ClariVein IC does not include medicants or agents. The ClariVein IC is not made of phthalate or latex material manufactured parts. It has been determined to be biocompatible for its intended use. The associated accessory includes a 5mL piston style, luer syringe as a convenience for the user.
Indications for Use	The ClariVein IC is indicated for the infusion of physician-specified agents in the peripheral vasculature (e.g., superficial veins, saphenous veins).
Comparison to Predicate Device	The subject ClariVein IC has the same overall basic design, controlling mechanism, energy source, technology, operating characteristics, materials and components as the predicate, currently marketed ClariVein IC. The reason for submitting this Special 510(k) is the addition of examples of peripheral vasculature to the indications for use statement. The intended use of the device is the same.
Safety & Performance Data	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. The fundamental scientific characteristics of the subject ClariVein IC are the same as the predicate device. No new performance testing was required to be conducted for the subject ClariVein IC. All materials of the subject device are used in the legally marketed predicate ClariVein IC with the same intended use, patient contact, processing and sterilization methods. No new biocompatibility testing was required for these materials. Clinical safety and performance information found in the literature, supplemented with post -market customer reported data, support the addition of examples of peripheral vasculature to the Indications for Use statement.
Summary of Substantial Equivalence	Based on the indications for use, design and materials, the subject ClariVein IC meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the ClariVein IC, K153502, manufactured by Merit Medical Systems, Inc.