November 3, 2021

Merit Medical Systems, Inc.
Kirk McIntosh
Regulatory Affairs Specialist II
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K212199
Trade/Device Name: ASAP® Aspiration Catheter, ASAPLP™ Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ
Dated: October 4, 2021
Received: October 5, 2021

Dear Kirk Mcintosh:

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)*
K212199

Device Name
ASAP® Aspiration Catheter (ASAP100);
ASAPLP™ Aspiration Catheter (ASAPLP)

Indications for Use *(Describe)*
The Merit ASAP® Aspiration Catheter is intended for the removal of fresh, soft emboli and thrombi from vessels of the arterial system. Not for use in cerebral vasculature.

The Merit ASAPLP™ Aspiration Catheter is intended for the removal of fresh, soft emboli and thrombi from vessels of the arterial system. Not for use in cerebral 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.**

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.***

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*"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."*

# Merit Medical ASAP® and ASAPLP™ 510(k) Summary **K212199**

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| **General Provisions** | Submitter Name: | Merit Medical Systems, Inc. |
| | Address: | 1600 West Merit Parkway<br>South Jordan, UT 84095 |
| | Telephone Number: | (801) 316-3695 |
| | Contact Person: | Kirk McIntosh |
| | Date Prepared: | July 13, 2021 |
| | Registration Number: | 1721504 |
| **Subject Device** | Trade Name: | ASAP® and ASAPLP™ Aspiration Catheters |
| | Common/Usual Name: | Embolectomy Catheter |
| | Classification Name: | Embolectomy Catheter |
| | Regulatory Class: | 2 |
| | Product Code: | QEZ |
| | 21 CFR §: | 870.5150 |
| | Review Panel: | Cardiovascular |
| **Primary Predicate** | Trade Name: | ASAP® Aspiration Catheter |
| | Classification Name: | Embolectomy Catheter |
| | Premarket Notification: | K100569 |
| | Manufacturer: | Merit Medical Systems, Inc. |
| | This predicate has not been subject to a design-related recall | |
| **Secondary Predicate** | Trade Name: | ASAPLP™ Aspiration Catheter |
| | Classification Name: | Embolectomy Catheter |
| | Premarket Notification: | K132155 |
| | Manufacturer: | Merit Medical Systems, Inc. |
| | This predicate has not been subject to a design-related recall | |

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| **Device Description** | The Merit ASAP aspiration Catheter is a dual lumen rapid exchange catheter, compatible with 0.014”/0.36 mm guide wires with related accessories. The catheter has a maximum outer diameter of 0.068”/1.73mm and a working length of 140 cm. The catheter has a radiopaque marker band located approximately 2 mm proximal to the distal tip. The catheter has three (3) non-radiopaque positioning marks located approximately 90 cm, 100 cm, and 110 cm proximal of the distal tip. The distal region has a hydrophilic coating. The rapid exchange lumen is 12cm in length.<br><br>The ASAPLP Aspiration Catheter is a dual lumen rapid exchange catheter, compatible with 0.014”/0.36 mm guide wires. It is packaged with related accessories including a stiffening stylet. The catheter has a maximum outer diameter of 0.055”/0.140 cm and a working length of 145cm. The catheter has a radiopaque marker band located approximately 2 mm proximal to the distal tip. The catheter has three (3) non-radiopaque positioning marks located approximately 90 cm, 100 cm and 110 cm proximal of the distal tip. The distal region has a hydrophilic coating. The rapid exchange lumen is 20 cm in length.<br><br>The associated accessories packaged with the device include:<br>• Tubing Connector Set with (1) Large Bore Stopcock<br>• RXP® Rapid Exchange Prep Syringe<br>• (2) 30 mL VacLok™ syringes<br>• Microstop Waste Basin with Lid and (2) 70 Micron Pore Filter Baskets |
| **Indications for Use** | The Merit ASAP® Aspiration Catheter is intended for the removal of fresh, soft emboli and thrombi from vessels of the arterial system. Not for use in cerebral vasculature.<br><br>The Merit ASAPLP™ Aspiration Catheter is intended for the removal of fresh, soft emboli and thrombi from vessels of the arterial system. Not for use in cerebral vasculature.<br><br>Note: There is no change in the Indications for Use statement from the predicate to the subject devices. |

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| **Comparison to Predicate Device** | The subject devices are substantially equivalent to the predicate devices based on an identical Indications for Use statement, the same basic performance and safety profile, principle of operation, fundamental design principles, and manufacturing technology.<br><br>The primary reason for submitting this Special 510(k) is the change to the Luer hub material formulation for both the ASAP and ASAPLP catheter configurations and update to the new ISO 80369-7 Luer standard.<br><br>There are no changes to the associated accessories. |
| **Performance Data** | No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject ASAP® and ASAPLP™ Aspiration Catheters was conducted based on the risk analysis and based on the requirements of the following international standards:<br><br>• ISO 10555-1:2013 *Intravascular catheters - Sterile and single-use catheters – Part 1: General requirements*<br>• ISO 80369-7:2021 *Small Bore Connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications*<br>• ISO 10993-1:2018, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (2020).<br>• ISO 10993-4: 2017, *Biological Evaluation of Medical Devices Part-4: Selection of Tests for Interactions with Blood*<br>• ISO 10993-5:2009 (Amd, 2017)*, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*<br>• ISO 10993-10:2013, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*<br>• ISO 10993-11:2017, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*<br>• United States Pharmacopeia (USP) 43-National Formulary (NF) 37: 2019 <151> Pyrogen Test. |
| **Safety & Performance Tests cont.** | The following performance data were provided in support of the substantial equivalence determination.<br><br>**Biocompatibility testing**<br>The biocompatibility evaluation for the ASAP® and ASAPLP™ Aspiration Catheters was conducted in accordance with ISO 10993-1 (2018), *Biological Evaluation of Medical Devices- Part 1: Evaluation* |

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| | *and testing within a risk management process* and the FDA guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (2020)*. The battery of testing included the following tests:<br><br>• Cytotoxicity<br>• Sensitization<br>• Irritation<br>• Acute Systemic Toxicity<br>• Pyrogenicity<br>• Hemolysis<br><br>The ASAP® and ASAPLP™ Aspiration Catheters are considered tissue contacting for a duration of less than 24 hours.<br><br><u>Performance Testing-Bench</u><br><br>• Force at break<br>• ISO 80369-7 Dimensional and functional testing<br><br>The results of the testing demonstrated that the subject ASAP® and ASAPLP™ Aspiration Catheters met the predetermined acceptance criteria applicable to the safety and efficacy of the device. |
| **Summary of Substantial Equivalence** | Based on the indications for use, design, safety and performance testing, the subject ASAP® and ASAPLP™ Aspiration Catheters meet the requirements that are considered essential for their intended use and are substantially equivalent to their predicate devices, the ASAP® and ASAPLP™ Aspiration Catheters, K100569 and K132155, manufactured by Merit Medical Systems, Inc. |