510(k) Summary

K190175

S-MAK XL™

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 316-4956 (801) 253-6982 David Thomas April 3, 2019 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	S-MAK XL™ Vessel Dilator/ Introducer Sheath Vessel Dilator for Percutaneous Catheterization
Primary Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Merit MAK® (Mini Access Kit) Vessel Dilator for Percutaneous Catheterization K091584 Merit Medical Systems, Inc.
Reference Devices	1.	K031691 – Merit MAK® (Mini Access Kit) (Manufacturer by Merit Medical Systems, Inc.)
	2.	K101604 – VSI Micro-Introducer (Manufacturer by VSI Solutions, Inc.)
Classification	Class II 21 CFR § 870.1310 FDA Product Code: DRE Review Panel: Cardiovascular	
Intended Use	The Merit S-MAK XL™ is intended for percutaneous placement of up to a 0.038” (.097mm) guide wire or catheter into the vascular system.	

Device Description	The S-MAK XL™ utilizes a small diameter coaxial introducer/dilator pair and guide wire for placement of larger diameter guide wires into the vasculature system when a small needle stick is preferred. The S-MAK XL™ consists of the following components: One (1) 4F Coaxial Introducer/Dilator Pair (30 cm length) One (1) 21 gauge Introducer Needle One (1) 0.018" (0.46mm) 80cm Nitinol/Palladium Guide Wire
Comparison to Predicate Device	• Design - The S-MAK XL™ will follow the same design as the current 4F, 10cm predicate Merit MAK device except for the increased length of 30cm for the Introducer/Dilator. • Materials - All materials for the 30cm S-MAK XL™ will remain the same as the predicate 4F, 10cm Merit MAK. • Processes - Process parameters will remain the same, with changes to the equipment as necessary to accommodate the longer length.
Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject S-MAK XL™ 4F 30cm was conducted based on the risk analysis and based on the requirements of the following international standards and guidance documents: ISO 11135:2014*, Sterilization of health care products – Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices.* *ISO 11070:1998, Sterile, single use intravascular catheter introducer.* ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*. FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995 ISO 10993-5:2009*, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity* ISO 10993-7:2008, *Biological Evaluation of Medical Devices – Part 7 Ethylene Oxide sterilization residuals* ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.*

AAMI/ANSI/ISO 11607-1:2006, Packaging for terminally sterilized medical devices – Part 1 – Requirements for materials, sterile barrier systems and packaging systems (Sterility)

ASTM D4169-16, Standards Practice for Performance Testing of Shipping Containers and Systems (Sterility)

ISO 2233 (2000), Packaging – Complete, filled transport packages and unit loads – conditions for testing

Performance Testing-Bench

- Effective Length – Introducer and dilator
- Guide wire insertion – dilator
- Catheter insertion – introducer

Passing results were demonstrated on all tests above.

Performance Tests cont.

Biocompatibility

- Cytotoxicity – Cytoxicity Study Using ISO Elation Method: MEM Extraction
- Sensitization – ISO Guinea Pig Maximization Test: Sodium Chloride and Sesame Oil Extraction
- Irritation – ISO Intracutaneous Study in Rabbits: Sodium Chloride and Sesame Oil Extraction
- Acute Systemic Toxicity _ ISO Acute Systemic Toxicity Study in Mice: Sodium Chloride and Sesame Oil Extraction
- Pyrogenicity – USP Rabbit Pyrogen Study, Material Mediated: Nonpyrogenic 0.9% Sodium Chloride Extraction
- Hemocompatiblity
  - ASTM Hemolysis Study – Direct Contact and Extract Method: Phosphate Buffered Saline Extraction
  - Indirect Contact Complement Activation Assay
  - In-vitro Assessment of Introducer Thrombosis.

Passing results were demonstrated on all tests above.

Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject S-MAK XL™ raises no new questions of safety and effectiveness compared to the predicate device and is substantially equivalent to the predicate device, the Merit MAK® (Mini Access Kit), K091584, manufactured by Merit Medical Systems, Inc.