

5.0 510(k) Summary K140513

JUL 09 2014

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) 208-4789 (801) 253-6919 Susan Christensen February 27, 2014 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Merit Safety Introducer Needles Safety Introducer Needle Catheter Introducer
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	SecureLoc™ Safety Introducer Needle Catheter Introducer K050023 Bard Access Systems, Inc.
Classification	Class II 21 CFR § 870.1340 FDA Product Code: DYB Review Panel: Cardiovascular	
Intended Use	The Merit Safety Introducer Needle is used for providing a puncture site in blood vessels for the introduction of vascular access devices. It also incorporates a safety mechanism to minimize needlestick injuries.	

**Device
Description**

The Merit Safety Introducer Needle is used for providing a puncture site in blood vessels for the introduction of vascular access devices. It incorporates a safety mechanism/guard to minimize needlestick injuries. The needle consists of a stainless steel one wall cannula and a clear standard female Luer lock hub for immediate bleed-back visualization. The hub of this introducer needle is designed with an ergonomic feel for ease of handling and is offered with a standard hub or a Seldinger shield. The needles are available in 18 gauge and 21 gauge with a usable length of 7 cm. The safety mechanism is color coded for needle gauge identification. The design of the Merit Safety Introducer Needle allows clinicians to easily activate the safety mechanism by advancing it to the end of the needle to shield the needle bevel after use. The safety mechanism automatically senses the end of the needle and locks the safety mechanism covering the needle tip which reduces the risk of accidental needlestick injuries by shielding the needle tip. A visual, tactile, and audible confirmation of the locking component over the needle confirms lockout of the safety guard over the needle. The safety mechanism cannot be deactivated and remains protective through disposal into a sharps container. The safety mechanism can be activated over guide wires. The Merit Safety Introducer Needle is a single use device that is supplied sterile and non-pyrogenic for use in the adult population.

**Comparison to
Predicate
Device**

The technological characteristics of the subject Merit Safety Introducer Needles are substantially equivalent to those of the predicate device. The needle is available in the same gauge sizes 18 and 21, same useable length 7 cm, and same hub styles which include with and without a Seldinger shield. The needle incorporates a clear standard female Luer lock hub for immediate bleed-back visualization and the safety mechanism is color coded for needle gauge identification.

- The Merit Safety Introducer Needles are similar in clinical use, function, materials and use to the predicate SecureLoc™ Safety Introducer Needles.
 - The Merit Safety Introducer Needles have a safety feature that locks a safety mechanism over the needle tip after the needle is removed from the patient, as does the SecureLoc Safety Introducer Needle predicate device.
 - The Merit Safety Introducer Needle's safety mechanism lock-out can be confirmed by visual means, tactile feel and audible means, as can the SecureLoc Safety Introducer Needle predicate device cited in this submission.
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No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Merit Safety Introducer Needles was conducted based on the risk analysis and based on the requirements of the following recognized and unrecognized international standards and FDA guidance documents:

**Safety &
Performance
Tests**

- FDA Guidance for Industry and FDA Staff, Medical Devices with Sharps Injury Prevention Features; August 9, 2005.
- ISO 7864:1993 – Sterile hypodermic needles for single use
- ISO 7864-2:1993 – Sterile hypodermic needles for single use Part 2: Specification for sterile hypodermic needles for single use
- ISO 594-1:1986 – Conical fittings with 6% (Luer) taper for syringes, needles, and certain other medical equipment Part1: General requirements
- ISO 594-2:1998 – Conical fittings with 6% (Luer) taper for syringes, needles, and certain other medical equipment Part2: Lock fittings
- ISO 6009:1992 – Hypodermic needles for single use – Color coding for identification
- ISO 9626:1992 Amendment 1:2001 – Stainless steel needle tubing for the manufacture of medical devices
- ISO 11070:1998 – Sterile single use intravascular catheter introducers
- ISO 11135-1 First Edition 2007, *Sterilization of health care products – Ethylene Oxide – part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995
- ISO 10993-4:2002 (Amd.1:2006), *Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood*
- 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*
- ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- ASTM F756-08:2008, *Standard Practice for Assessment of Hemolytic Properties of Materials*
- United States Pharmacopeia Section <151>, USP 36 Pyrogen Testing, 2013-12-01

Performance Testing-Bench

**Safety &
Performance
Tests cont.**

- Dimensions
- Puncture Resistance Testing
- Force to Defeat Safety Mechanism Testing
- Force to Activate Safety Mechanism Testing
- Hub to Cannula Bond Strength Test
- Visual Inspection
- Luer Gauging Test
- Luer Liquid Leak Test
- Luer Air Aspiration Leak Test
- Luer Separation Force Test
- Luer Unscrewing Torque Test
- Luer Ease of Assembly Test
- Luer Resistance to Overriding Test
- Luer Stress Cracking Test
- Needle Penetration Testing
- Guide Wire Compatibility
- Corrosion Resistance
- Simulated Use Testing

Biocompatibility

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hematology
- Coagulation
- Hemolysis
- Chemical Characterization

**Summary of
Substantial
Equivalence**

Based on the indications for use, design, safety and performance testing, the subject Merit Safety Introducer Needles meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, SecureLoc Safety Introducer Needle, K050023.



July 9, 2014

Merit Medical Systems, Incorporated
Ms. Susan Christensen
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K140513
Trade/Device Name: Merit Safety Introducer Needles
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: II
Product Code: DYB
Dated: June 18, 2014
Received: June 19, 2014

Dear Ms. Christensen:

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" (21CFR 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,

 Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140513

Device Name

Merit Safety Introducer Needle

Indications for Use (Describe)

The Merit Safety Introducer Needle is used for providing a puncture site in blood vessels for the introduction of vascular access devices. It also incorporates a safety mechanism to minimize needlestick injuries.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



Digitally signed by Richard
C. Chapman -S
Date: 2014.07.09 12:09:08
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