

K022117

**Merit Medical Systems, Inc.**  
**Majestik® Shielded Angiography Needle**  
**PREMARKET NOTIFICATION [510(k)]**  
**CONFIDENTIAL**

OCT 11 2002

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**Name of Medical Device:**

Classification Name: Needle, Angiographic  
Common/Usual Name: Angiography Needle  
Trade/Proprietary Name: Majestik Shielded Angiography Needle

**Device Classification:**

Panel: Cardiovascular  
Class: II  
Product Code: 74 HAQ  
Regulation Number: 21 CFR 870.1390

**Predicate Devices:**

**Predicate 1**

Device/Trade/Proprietary Name: Majestik® Angiography Needle  
Common/Usual Name: Angiography Needle  
Classification Name: Needle, Angiographic  
21 CFR 870.1390  
Classification Panel: Cardiovascular  
Regulatory Status: Legally Marketed pre-Amendment

**Predicate 2**

Device/Trade/Proprietary Name: Axia RSN™ Guidewire Introducer Safety Needle  
Common/Usual Name: Guidewire Introducer Needle  
Classification Name: Catheter Introducer  
21 CFR 870.1340  
Classification Panel: Cardiovascular  
Regulatory Status: Legally Marketed via K011085

**Predicate 3**

Device/Trade/Proprietary Name: B-D SafetyGlide™ Shielding IM Injection Needle  
Common/Usual Name: Hypodermic Needle  
Classification Name: Hypodermic Single Lumen Needle  
21 CFR 880.5570  
Classification Panel: General Hospital  
Regulatory Status: Legally Marketed via K951254

**Device Description:**

The Merit Majestik Shielded Angiography Needle is a safety-engineered angiography needle that is used for providing a puncture site in blood vessels for the introduction of vascular access devices. The needle incorporates an integral, user-activated needle shield (safety feature) that is activated once a conventional vessel puncture procedure has concluded. The Majestik Shielded Angiography Needle will provide clinicians with a safety version of the legally marketed pre-amendment Majestik Angiography Needle (or equivalent) currently used during Cardiology and Radiology procedures.

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The Majestik Shielded Angiography Needle incorporates a clear standard female luer locking connector for immediate bleedback visualization and is color coded for needle gauge identification. A one-piece, color coded folding needle shield, linked with “living hinges” is bonded to the female luer locking connector. The needle shield is color coded to match the luer connector for immediate needle gauge identification. The Majestik Shielded Angiography Needle is offered with the needle shield in two orientations: 1) oriented vertically to the ground bevel side of the needle; or 2) oriented 90 degrees to the ground bevel side of the needle. The Majestik Shielded Angiography Needle is a single use device supplied sterile and non-pyrogenic.

**Intended Use:**

The Merit Majestik Shielded Angiography Needle is used for providing a puncture site in blood vessels for the introduction of vascular access devices.

The Merit Majestik Shielded Angiography Needle incorporates a safety mechanism to minimize needlestick injuries when used to access the vascular system.

**Summary of Characteristics in Relation to Predicate Devices:**

**Does the new device have the same indication statement:**

**Yes.** The Majestik Shielded Angiography Needle has the same indication statement as the Axia RSN™ Guidewire Introducer Safety Needle. The Majestik Shielded Angiography Needle has the same indications as the original pre-Amendment Majestik Angiography Needle without the needle shield.

**Does the new device have the same technological characteristics, e.g., design, material, etc.?**

**Not in all respects.** The Majestik Shielded Angiography Needle compares technologically to the predicate devices as follows.

**Predicate 1 - Majestik Angiography Needle:** The Majestik Shielded Angiography Needle is identical in all aspects to the Majestik Angiography Needle except that the subject device incorporates a needle shield safety feature.

**Predicate 2 - Axia RSN™ Guidewire Introducer Safety Needle:** The Majestik Shielded Angiography Needle differs somewhat in design, materials, and methods of operation. The safety feature retracts the needle within an open-ended sheath when the safety feature activation button is pushed.

**Predicate 3 - B-D SafetyGlide™ Shielding IM Injection Needle:** The Majestik Shielded Angiography Needle employs similar method of operation, design, and materials when compared to the B-D device. Both incorporate a folding needle shield which, when activated by the user, snaps into place covering the needle tip.

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**Could the new characteristics affect safety or effectiveness?**

**Yes.** The addition of a needle shield to the original Majestik Angiography Needle could affect the safety or effectiveness of the device.

**Do the new characteristics raise new types of safety and effectiveness questions?**

**No.** The safety and effectiveness questions are the same for all needles of this type.

**Do accepted scientific methods exist for assessing effects of the new characteristics?**

**Yes.** The FDA's *Supplementary Guidance On The Content Of Premarket Notification [510(k)] Submissions For Medical Devices With Sharps Injury Prevention Features*, dated March 1995, and various recognized standards as well as in-house test protocols were used to evaluate the device's performance.

**Are performance data available to assess effects of the new characteristics?**

**Yes.** Bench and simulated use tests were conducted according to the above referenced guidance document recommendations, as well as in accordance with in-house protocols. The results of testing were compared to the predicate devices where appropriate.

Those tests applicable to the type of safety device and safety features of the Majestik Shielded Angiography Needle per the *Supplementary Guidance On The Content Of Premarket Notification [510(k)] Submissions For Medical Devices With Sharps Injury Prevention Features* were performed as follows.

- Dimensions
- Strength of bonds and hinges
- Force to activate the safety feature
- Puncture resistance of shield or sheath: the force to failure (puncture)
- Biocompatibility
- Simulated Clinical Use

The Majestik Shielded Angiography Needle met all acceptance criteria of the tests performed.

**Do performance data demonstrate equivalence?**

**Yes.** Performance data demonstrated that the Majestik Shielded Angiography Needles are substantially equivalent to the predicate devices and/or met acceptance criteria as defined in testing protocols. The risks associated with use of the Majestik Shielded Angiography Needle were found acceptable when evaluated by FMEA.

**CONCLUSION:**

The Majestik Shielded Angiography Needle met all acceptance criteria of the testing performed and, based upon FDA's substantial equivalence determination decision tree, is substantially equivalent to the predicate devices referenced in this summary.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Merit Medical Systems, Inc.  
Ms. Stephanie A. Erskine  
Regulatory Affairs Director  
1600 West Merit Parkway  
South Jordan, UT 84095

**OCT 11 2002**

Re: K022117  
Trade Name: Majestik® Shielded Angiography Needle  
Regulation Number: 21 CFR 870.1390  
Regulation Name: Trocar  
Regulatory Class: II  
Product Code: DRC  
Dated: September 25, 2002  
Received: September 26, 2002

Dear Ms. Erskine:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set

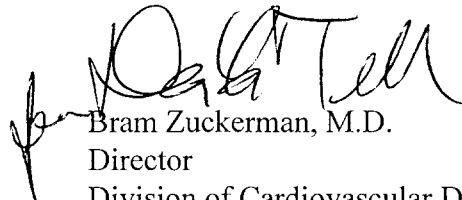
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram Zuckerman". The signature is stylized and written over the printed name.

Bram Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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Section 7

Statement of Indications for Use

510(k) Number (if known): K022117

Device Name: **Majestik Shielded Angiography Needle**


Indications for Use:

- The Merit Majestik® Shielded Angiography Needle is used for providing a puncture site in blood vessels for the introduction of vascular access devices. The needle incorporates a safety mechanism to help minimize needlestick injuries after use.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED.)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K022117

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-the Counter Use \_\_\_\_\_