K113737

FEB 23 2012

Owner/Manufacturer:	Owner Surefire Medical, Inc. 8601 Turnpike Dr. Suite 206 Westminster, CO 80031	Manufacturer Surefire Medical, Inc. 12415 SW 136 Avenue Unit 3 Miami, FL 33186
Contact Person:	Mario Arbesu Director, Quality Assurance and Regulatory Affairs 305.378.2651	
Date of Summary Preparation:	24 January 2012	
Trade Name:	Surefire® Guide Sheath	
Common Name:	Intravascular Catheter	
Classification Name:	Intravascular Diagnostic Catheter	
Classification:	Class II	
Classification Regulation:	21 CRF Part 870.1200 - Diagnostic intravascular catheter.	
Product Code:	DQO	
Intended Use:	The Surefire® Guide Sheath is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.	
Device Description:	The Surefire® Guide Sheath is designed to act as a conduit for diagnostic agents and facilitates deployment at the desired treatment location. The Guide Sheath is a 0.035" guide wire compatible, single lumen, fixed length catheter body with a luer lock hub.	
Principals of Operation/ Technology:	The Surefire® Guide Sheath is operated manually.	

Performance Testing & Verification Testing

The following series of tests have been provided in this submission:

- Kink Testing
- Tensile Testing
- High Pressure Injection Testing
- Trackability Testing
- Torque Testing
- Dimensional Inspection

Testing listed below was provided in the original submission. The modifications in this device have no impact on these characteristics:

- Kink Testing
- Hub Aspiration Testing
- Embolic Agent Infusion Compatibility Testing
- Package Integrity Testing
- Corrosion Testing
- Diagnostic Agent Compatibility Testing
- Coating Integrity
- Antegrade Flow Testing
- Infusion Efficiency

- Biocompatability
  - Hemolysis – ASTM F756 and ISO 10993-4
  - Cytotoxicity – ISO 10993-5
  - Intra-cutaneous Irritation – ISO 10993-10
  - Sensitization – ISO 10993-10
  - Pyrogenicity – ISO 10993-11
  - Particulate – USP Standards
  - Complement System was performed

Performance/Safety: A risk/hazard analysis was conducted according to EN ISO 14971 Medical Devices- Application of Risk management to medical devices. Performance characteristics for this indication for use were determined. It was then justified that the performance of the Surefire® Guide Sheath is substantially equivalent to the performance and safety of the Surefire® Infusion System. A battery of tests was performed according to protocols based on the requirements of the international standards and was shown to meet the acceptance criteria that were determined to be applicable to the safety and efficacy of the device.

Additional Safety Information: Manufacturing controls include visual, functional, dimensional and sterility tests. Blood contacting materials were tested in accordance with the tests recommended in the FDA General program Memorandum. Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part -1 Evaluation and testing".

Substantial Equivalence: The Surefire® Guide Sheath is substantially equivalent in intended use, design, technology/principles of operation to the predicate. The Guide sheath is substantially equivalent to the Surefire Infusion System, cleared under K110459.

Differences between the devices do not raise any significant issues of safety or effectiveness.

Submitter Information:

Prepared by: Mario Arbesu
Director, Quality Assurance and Regulatory Affairs

Prepared for: Surefire Medical, Inc.
12415 SW 136 Avenue
Unit 3
Miami, FL 33186

Date: January 24, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Surefire Medical, Inc.
c/o Mr. Mario Arbesu
Director, Quality Assurance and Regulatory Affairs
8601 Turnpike Drive
Suite 206
Westminster, CO 80031

FEB 23 2012

Re: K113737
Trade Name: Surefire® Guide Sheath
Regulation Number: 21 CFR 870.1200
Regulation Name: Intravascular Diagnostic Catheter
Regulatory Class: II (two)
Product Code: DQO
Dated: January 24, 2012
Received: January 26, 2012

Dear Mr. Arbesu:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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 Small Manufacturers, International and Consumer Assistance 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,

M. G. Hillebrenner

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

Enclosures

Indication for Use

510(k) Number (if known): K113737

Device Name: Surefire® Guide Sheath

Indication for Use: The SUREFIRE® GUIDE SHEATH is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

Prescription Use ___X_____ AND/OR Over-The-counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH,

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113737