K121677

JUN 14 2012

Owner/Manufacturer:	Owner Surefire Medical, Inc. 8601 Turnpike Dr. Suite 206 Westminster, CO 80031	Manufacturer Surefire Medical, Inc. 12415 SW136 Avenue Unit 3 Miami, FL 33186
Contact Person:	Mario Arbesu Director, Quality Assurance and Regulatory Affairs 305.378.2651	
Date of Summary Preparation:	26 April 2012	
Trade Name:	Surefire® Hi-Flow Microcatheter	
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® Hi-Flow Microcatheter 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® Hi-Flow Microcatheter is an 0.027" lumen microcatheter with the Surefire Expandable Tip at the distal end. It has an outer sheath to facilitate deployment and retraction of the Surefire Expandable Tip. The infusion catheter serves as the conduit for physician-specified agents such as contrast agents, flush solutions, and embolic beads. It is compatible with standard 0.018" guide wires, infusion syringes, rotating hemostatic valves (RHVs), and embolic particles 700μm or less in size. The proximal end of the device features a female luer lock hub. The microcatheter has a Teflon inner liner to provide a lubricious surface for passage of physician-specified agents and other accessory devices. The outer sheath is hydrophilically coated. The usable length of the device is 120cm. The distal soft, pliable, funnel-shaped Surefire Expandable Tip is available	

in two tip sizes, targeted to treat vessels of 3.0 - 4.5 mm and 4.0 - 6.0 mm.

Principals of Operation/ Technology: The Surefire® Hi-Flow Microcatheter is operated manually.

Performance Testing & Verification Testing

- Kink Radius Testing
- Trackability Testing
- Pull Strength Testing
- High Pressure Injection Testing
- Infusion Agent Compatibility Testing
- Package Integrity (Pouch Bubble) Testing
- Device Corrosion Testing
- Antegrade Flow Testing
- Infusion Efficiency Testing
- Visual and Dimensional Inspections
- Coating Integrity Testing
- Particulate Testing
- Tensile Testing
- Torque Testing
- Shelf Life Testing

Biocompatibility Testing

- **Cytotoxicity** – Tested in accordance with ISO 10993-5
- **Sensitization** – Tested in accordance with ISO 10993-10
- **Intra-cutaneous irritation** – Tested in accordance with ISO 10993-10
- **Toxicity** – Tested in accordance with ISO 10993-11
- **Pyrogenicity** – Tested in accordance with USP General Chapter <151> Pyrogen Test recommended in ISO 10993-11
- **Hemolysis** – Tested in accordance with ASTM F756 and ISO 10993-4
- **Coagulation** – Tested in accordance with ASTM F2382
- **Particulate** – Tested in accordance with USP 788
- **Complement System** – Testing 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 identified which included a review of both ISO 10555-1 (Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements) and ISO 10555-2 (Sterile, single-use intravascular catheters – Part 2: Angiographic catheters). It was then determined that the performance of the Surefire® Hi-Flow Microcatheter is substantially equivalent to the performance and safety of the Surefire® Infusion Catheter System. A battery of tests was performed according to protocols based on the requirements of recognized 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® Hi-Flow Microcatheter is substantially equivalent in intended use, design, and technology/principles of operation to the predicate. Both devices share the same Indications for Use. Both devices make use of the Surefire Expandable Tip at the distal end of the microcatheter to increase the infusion efficiency of the device while maintaining sufficient antegrade flow. Both systems are compatible with solutions containing embolic agents, specifically hydrogels ≤ 700 μm and glass beads ≤ 190 μm. Both devices include configurations intended for use in vessels of 4.0 – 6.0 mm in diameter. The proposed device contains an additional configuration for use in vessels of 3.0 – 4.5 mm in diameter. The Microcatheter is substantially equivalent to the Surefire® Infusion Catheter System, cleared under K110459. Differences between the devices do not raise any issues of safety or effectiveness.

Test data provided in bench tests demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the predicate device.

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: April 26, 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

JUN 14 2012

Surefire Medical, Inc.
c/o Mark Job
Responsible Third Party Official
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K121677
Trade/Device Name: Surefire Hi-Flow Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (Two)
Product Code: DQO
Dated: June 6, 2012
Received: June 7, 2012

Dear Mr. Job:

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" (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 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. Hillebren

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

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: Surefire® Hi-Flow Microcatheter

Indication for Use: The SUREFIRE® HI-FLOW MICROCATHETER 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 (part 21 CFR 801 Subpart D) AND/OR Over-The-counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121677