DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 21, 2016

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

Re: K162359
Trade/Device Name: Surefire Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Procode: DQY
Dated: August 19, 2016
Received: August 23, 2016

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 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,

Brian D. Pullin -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162359

Device Name
Surefire Guiding Catheter

Indications for Use *(Describe)*
The Surefire Guiding Catheter is intended to provide a pathway through which therapeutic devices are introduced. The Surefire Guiding Catheter is intended to be used in the peripheral vascular system.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

(DATE PREPARED: AUGUST 9, 2016)

Device Name
Surefire Guiding Catheter

Manufacturer Name and Address
Surefire Medical, Inc.
6272 W. 91st Avenue
Westminster, CO 80031
Owner Operator Number: 10038066

Submitter Contact Information
Surefire Medical, Inc.
Surefire Medical, Inc.
6272 W. 91st Avenue
Westminster, CO 80031
Contact: Lynne Aronson, VP Regulatory Affairs and Quality Assurance
Phone: 303-426-1222 Fax: 303-426-1223

Common, Classification & Proprietary Names

Common Name:	Guiding Catheter
Classification Name:	Percutaneous Catheter
Proprietary Name:	Surefire Guiding Catheter
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Classification Regulation:	21 CFR 870.1250
Product Code:	DQY

Predicate Device
- Surefire Guiding Catheter K140034

Device Description
The Surefire Guiding Catheter provides a pathway to introduce and facilitate the advancement of devices into the peripheral vascular system.

The Surefire Guiding Catheter is a single-lumen 5F catheter with a soft distal tip and a Luer-Lock hub and strain relief. The Surefire Guiding Catheter has a three-layer construction, consisting of a Teflon inner liner, metal mid-layer, and a polymer outer shaft jacket. The polymer is filled with a radiopacifier agent, to provide visibility of the catheter under fluoroscopy.

The Surefire Guiding Catheter is available in 65 cm and 80 cm lengths with a variety of pre-shaped tip designs (including but not limited to Axis and Sim1) to accommodate access and positioning in a range of peripheral vascular anatomies.

The Surefire Guiding Catheter is compatible with standard 0.038" OD guide wires, Luer-Lock infusion syringes, rotating hemostatic valves (RHV), and 5F catheter sheath introducers.

The Surefire Guiding Catheter is provided sterile (EtO) for single patient use.

Indications for Use

The Surefire Guiding Catheter is intended to provide a pathway through which therapeutic devices are introduced. The Surefire Guiding Catheter is intended to be used in the peripheral vascular system.

Biocompatability Testing

The patient contact materials and colorants used to fabricate the proximal section (hub and shaft) of the modified Surefire Guiding Catheter are identical to the Surefire Guiding Catheter as it was cleared in 510(k) K140034 (cleared February 26, 2014) in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.). Biocompatibility testing of the patient-contact materials used in the construction of the proximal section (hub and shaft) of the modified Surefire Guiding Catheter were previously performed in accordance with ISO 10993-1 for an external communicating device in contact with circulating blood with a limited duration of less than 24 hours. The testing was conducted in accordance with GLP by NAMSA (Northwood, OH). Therefore, the biocompatibility test requirements for the proximal section (hub and shaft) of the modified Surefire Guiding Catheter were met by leveraging the previously completed biocompatibility testing.

Biocompatibility testing of the patient contact materials used to fabricate the modified distal tip was performed in accordance with GLP (NAMSA, Northwood, OH) and ISO 10993-1 for external communicating devices in contact with circulating blood with a limited duration of less than 24 hours.

Biocompatibility testing of the material used to jacket the catheter shaft was completed by the material manufacturer in accordance with GLP (Toxicon, Bedford MA) and ISO 10993-1 for external communicating devices in contact with circulating blood with a limited duration of less than 24 hours.

Additionally, testing for thrombogenicity was performed on the modified Surefire Guiding Catheter as a part of an Animal Study.

The results of all of the biocompatibility testing did not indicate any significant biological reaction that would affect the patient due to contact with the materials used in the device construction.

Biocompatibility Testing ISO 10993-1 for external communicating devices in contact with circulating blood, duration < 24 hours		
Category	**Standard**	**Test Method**
Cytotoxicity	ISO 10993-5	Cytotoxicity Study Using the ISO Elution Method – 1x Minimal Essential Media Extract
Sensitization	ISO 10993-10	ISO Maximization Sensitization Study – Extract – 0.9% Sodium Chloride Solution Extract – Sesame Oil, NF Extract
Irritation or Intracutaneous Reactivity	ISO 10993-10	ISO Intracutaneous Study – Extract – 0.9% Sodium Chloride Solution Extract – Sesame Oil, NF Extract
Systemic Toxicity	ISO 10993-11	ISO Systemic Toxicity Study – Extract – 0.9% Sodium Chloride Solution Extract – Sesame Oil, NF Extract
		Pyrogen – Material Mediated – 0.9% Sodium Chloride Solution Extract
Hemocompatability	ISO 10993-4	ASTM Hemolysis – CMF-PBS Extract
		C3a Complement Assay – Normal Human Serum Extract
		SC5b-9 Complement Assay – Normal Human Serum Extract
		Coagulation – ASTM Partial Thromboplastin Time

Performance Testing

The following design verification / validation tests were performed as a result of the risk analysis assessment of the dimensional modifications. The test results demonstrate that the modified Surefire Guiding Cathater meets the same performance specifications and acceptance criteria as the predicate device.

- Visual Inspection / Distal Kink
- Dimensional Inspection
- Proximal Kink
- Pull Strength
- Trackability/ Device Compatibility
- Torque
- High Pressure Injection (Burst)
- Corrosion
- Particulate

The following testing was leveraged from previous testing of the predicate device:

- Packaging and Labeling Visuals
- Packaging Integrity (Pouch Bubble)
- Pouch Seal Strength
- Diagnostic Agent Compatibility
- Hub Aspiration
- Flow Rates and Associated Pressures

Animal Testing

A GLP animal study was performed to assess the comparative acute performance of the Surefire Guiding Catheter to the predicate device, as defined by a physician in a clinical environment. The Surefire Guiding Catheter was found to have acceptable performance. Additionally, the Surefire Guiding Catheter was found to have comparable performance to the predicate device.

Substantial Equivalence

The Surefire Guiding Catheter is substantially equivalent in intended use, design, and technology/principles of operation to the predicate device.

Comparative Summary: Design / Technological Characteristics

The modified Surefire Guiding Catheter and predicate devices are single-lumen 5F catheters with a soft distal tip and a Luer-Lock hub and strain relief. Both the modified and predicated devices have a multi-layer construction, consisting of a Teflon inner liner, metal mid-layer, and a polymer outer shaft jacket filled with a radiopacifier agent.

Both the modified and predicate Surefire Guiding Catheters are available in 65 cm and 80 cm lengths with a variety of pre-shaped tip designs, and are compatible with standard 0.038” OD guide wires, Luer-Lock infusion syringes, rotating hemostatic valves (RHV), and 5F catheter sheath introducers.

Both the modified and predicate Surefire Guiding Catheter are provided in identical packaging, sterilized by ethylene oxide, and labeled for single use only.

Comparative Summary: Indications for Use

The indication statement of the modified Surefire Guiding Catheter is the same as that of the predicate device. Both devices are intended to provide a pathway through which therapeutic devices are introduced in the peripheral vascular system.

Comparative Summary: Performance

Animal and bench performance test data demonstrate that the Surefire Guiding Catheter performance is comparable to the predicate device.

In summary, the modified Surefire Guiding Catheter is substantially equivalent in intended use, design, and technology/principles of operation to the predicate device. Animal and bench performance test data demonstrate that the modified Surefire Guiding Catheter performance is comparable to the predicate device. Differences between the devices do not raise any issues of safety or effectiveness.