



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

March 11, 2016

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

Re: K160662

Trade/Device Name: Surefire Infusion System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Dated: March 7, 2016
Received: March 9, 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,

Kenneth J. Cavanaugh -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K160662

Device Name

Surefire Infusion System

Indications for Use (Describe)

The Surefire Infusion System is intended for use in angiographic procedures.

It delivers radiopaque media and therapeutic agents to selected sites 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

(DATE PREPARED: MARCH 2, 2016)

Device Name

Surefire Infusion System

Manufacturer Name and Address

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

Submitter Contact Information

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:	diagnostic intravascular catheter
Classification Name:	diagnostic intravascular catheter
Proprietary Name:	Surefire Infusion System
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Classification Regulation:	21 CFR 870.1200
Product Code:	DQO

Predicate Device

- Surefire Infusion System 021 K143588
(marketed as Surefire Precision Infusion System)

Device Description

The modified Surefire Infusion System is a 0.027" lumen coaxial microcatheter with the Surefire Expandable Tip at the distal end. The Surefire Infusion System has a female luer lock hub on the proximal end of the catheter and has a catheter shaft length of 150 cm.

The modified Surefire Infusion System 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/Tuohy Borsts), and embolic hydrogel particles 700µm or less in size and glass microspheres 190µm or less in size. The Surefire Infusion System, serves as the conduit for physician-specified agents such as contrast agents, flush solutions, and embolic beads. The Surefire Infusion System has a Teflon inner liner to provide a lubricious surface for passage of physician-specified agents and other accessory devices. The device is hydrophilically coated. The soft, pliable, funnel-shaped Surefire Expandable Tip is sized for use in vessels of 4 mm to 6 mm.

The Surefire Infusion System has an outer sheath to facilitate expanding and collapsing the Surefire Expandable Tip. There are three radiopaque markers located just proximal and distal to the Surefire Expandable Tip. The Tip can be expanded or collapsed for re-positioning during an interventional procedure by simply retracting or advancing the inner microcatheter while holding the outer sheath stationary. When expanded, the Expandable Tip is designed to improve infusion efficiency of compatible embolic agents while maintaining antegrade flow in the vessel.

The Surefire Infusion System is provided sterile (EtO) for single patient use.

Indications for Use

The Surefire Infusion System is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

Biocompatibility Testing

All of the patient-contact materials used to fabricate the modified Surefire Infusion System are identical to the predicate Surefire Infusion System as it was approved in 510(k) K143588 (cleared January 12, 2015) 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 modified Surefire Infusion System 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).

As the modified Surefire Infusion System is constructed of the same materials as the predicate Surefire Infusion System, the biocompatibility test requirements for the modified Surefire Infusion System were met by leveraging the previously completed biocompatibility testing listed below.

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

The results 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.

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
		ISO Maximization Sensitization Study – Extract – Sesame Oil, NF Extract
Irritation or Intracutaneous Reactivity	ISO 10993-10	ISO Intracutaneous Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Intracutaneous Study – Extract – Sesame Oil, NF Extract
Systemic Toxicity	ISO 10993-11	ISO Systemic Toxicity Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Systemic Toxicity Study – Extract – Sesame Oil, NF Extract
		Pyrogen – Material Mediated – 0.9% Sodium Chloride Solution Extract
Hemocompatibility	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 Infusion System meets the same performance specifications and acceptance criteria as the predicate device.

- | | |
|----------------------------------|-------------------------------------|
| ▪ Visual/Dimensional Inspections | ▪ Kink Resistance |
| ▪ Pull Force | ▪ Antegrade Flow |
| ▪ Infusion Efficiency | ▪ Torque Resistance (catheter body) |
| ▪ Particulates | ▪ Trackability |
| ▪ Device Compatibility | |

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

- | | |
|--|---|
| ▪ Packaging seal strength and integrity | ▪ Burst Pressure |
| ▪ Hub Aspiration | ▪ Diagnostic Infusion Agent Compatibility |
| ▪ Corrosion | ▪ Embolic Agent Compatibility |
| ▪ Pull Force (handle components) | ▪ Torque (handle components) |
| ▪ Hydrophilic Coating Lubricity and Wear | |

Animal Testing

An animal study was performed to assess the comparative acute performance of the modified Surefire Infusion System to the predicate device, as defined by physicians in a simulated clinical environment. The modified Surefire Infusion System was found to be acceptable in all evaluated categories, met the defined user needs, and performed comparably to the predicate device.

Substantial Equivalence

The modified Surefire Infusion System is substantially equivalent in intended use, design, and technology/principles of operation to the predicate.

Comparative Summary: Design / Technological Characteristics

The modified Surefire Infusion System and predicate device are coaxial microcatheters with the Surefire Expandable Tip at the distal end. Both infusion systems have an outer catheter to facilitate expanding and collapsing the Surefire Expandable Tip.

The modified Surefire Infusion System and the predicate device are constructed of the same materials utilizing similar construction and manufacturing processes.

The modified Surefire Infusion System is a larger version of the predicate device. The predicate device has an inner lumen diameter of .021", length of 120 cm, and a Surefire Expandable Tip sized for use in vessels 1.5 – 3.5 mm. The modified device has an inner lumen diameter of .027", lengths of 150 cm, and a Surefire Expandable Tip sized for use in vessels 4-6 mm.

The modified Surefire Infusion System and predicate device are provided in identical packaging, sterilized by ethylene oxide, and labeled for single use only.

Comparative Summary: Indications for Use

The modified Surefire Infusion System has the same indications for use as the predicate device. Both devices are intended for use in angiographic procedures to deliver radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

Comparative Summary: Performance

Animal and bench performance test data demonstrate that the modified Surefire Infusion System performance is comparable to the predicate device.

In summary, the modified Surefire Infusion System 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 Infusion System performance is comparable to the predicate device. Differences between the devices do not raise any issues of safety or effectiveness.