April 3, 2018

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

Re: K180677
Trade/Device Name: Surefire Spark Infusion System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: March 13, 2018
Received: March 15, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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)*
K180677

Device Name
Surefire Spark Infusion System

Indications for Use *(Describe)*
The Surefire Spark 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.

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510(K) SUMMARY

(DATE PREPARED: APRIL 2, 2018)

K180677

Device Name
Surefire® Spark™ 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® Spark™ Infusion System
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Classification Regulation:	21 CFR 870.1200
Product Code:	DQO

Predicate Device
- Surefire Precision Infusion System (also marketed as Surefire Infusion System) K171355

Device Description
The Surefire Spark Infusion System is a 0.021" lumen microcatheter with a self-expanding tip at the distal end. The Surefire Spark serves as the conduit for physician-specified agents such as contrast agents, flush solutions, and embolic beads. It is compatible with standard guide wires up to 0.018", and embolic hydrogel particles 500µm or less in size and glass microspheres 110µm or less in size. The Surefire Spark has a PTFE 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, self-expanding tip is sized for use in vessels of 1.5-3.5mm.

There are two radiopaque markers located at the distal end of the Surefire Spark to aid in positioning of the self-expanding tip. When in correct position, the self-expanding tip is designed to improve infusion efficiency of compatible embolic agents while maintaining antegrade flow in various size vessels.

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

The Surefire Infusion Systems will be available in the following sizes:

Inner Diameter	Length	Tip / Vessel Size
0.021 inch	120 cm	1.5 – 3.5 mm
0.021 inch	150 cm	1.5 – 3.5 mm

Indications for Use

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

Substantial Equivalence

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

Comparative Summary: Design / Technological Characteristics

The Surefire Spark Infusion System is similar in design to the predicate device. Both devices are microcatheters with an expandable tip on the distal end. The Surefire Spark is a single microcatheter, whereas the predicate device is a coaxial (dual) microcatheter. The Surefire Spark has a self-expanding tip, in comparison to the predicate device which has a manual mechanism in the device handle to expand and collapse the tip. An introducer on the Surefire Spark is used to collapse the tip so that it can be introduced into the guide catheter.

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

The Surefire Spark Infusion System and the predicate device have similar dimensions.

The Surefire Spark 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 Surefire Spark 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 Surefire Spark Infusion System performance is comparable to the predicate device.

Biocompatibility Testing

Biocompatibility testing was not conducted on the subject device. Testing was leveraged from the Surefire High Flow Microcatheter (K121677), Surefire Guiding Catheter (K162359), and Surefire Precision Infusion System (K171355). Testing for thrombogenicity was performed on the Surefire Spark Infusion System Catheter as a part of an Animal Study.

Performance Testing

The following design verification / validation tests were performed. The test results demonstrate that the Surefire Spark Infusion System meets the same performance specifications and acceptance criteria as the predicate device.

- Visual and Dimensional
- Tensile (Pull) Strengths
- Kink Radius
- Torque Resistance
- Burst Pressure
- Coating Frictional Force
- Base Catheter Insertion/Retraction Force
- Diagnostic Agent Compatibility
- Embolic Agent Compatibility
- Infusion Efficiency

- Hub Aspiration
- Corrosion Resistance
- Hub Solvent Compatibility
- Coating Durability and Uniformity
- Antegrade Flow
- Particulates
- Pouch Integrity
- Pouch Seal Strength

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

- EtO Residuals

Animal Testing

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

Conclusion

In summary, the Surefire Spark 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 Surefire Spark Infusion System performance is comparable to the predicate device. Differences between the devices do not raise different questions of safety and effectiveness.