DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 3, 2016

Stryker Corporation
Somi Ekwealor
Regulatory Affairs Analyst
5900 Optical Court
San Jose, California 95138

Re: K160050
Trade/Device Name: SERFAS 90-S Electrosurgical Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 1, 2016
Received: April 4, 2016

Dear Somi Ekwealor:

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" (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 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K160050

Device Name
Stryker® SERFAS 90-S Electrosurgical Probe

Indications for Use *(Describe)*
The Stryker SERFAS 90-S Electrosurgical Probe is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic and arthroscopic procedures of joints such as the knee, shoulder, elbow, hip, ankle, and wrist.

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
PRAStaff@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."

1. General Information

510(k) Sponsor	Stryker Corporation
Address	5900 Optical Court San Jose, CA 95138
FDA Registration Number	2936485
Correspondence Person	Mr. Somi Ekwealor, MSRS, RAC Regulatory Affairs Analyst Stryker Corporation
Contact Information	Email: somi.ekwealor@stryker.com Phone: (408) 754-2356 Fax: (408) 754-2507
Date Prepared	08 Jan 2016

2. Device Identification

Proposed Device:

Proprietary Name	Stryker® SERFAS 90-S Electrosurgical Probe
Common Name	RF Probe
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number	21 CFR 878.4400
Product Code	GEI
Regulatory Class	II

Predicate Device:

Proprietary Name	SERFAS Energy System (probe only*)
Common Name	RF System, RF Generator, RF Probe, RF Footswitch
Premarket Notification	K041810
Classification Name	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number	21 CFR 878.4400
Product Code	GEI
Regulatory Class	II

* The predicate device includes the entire energy system and accessories while the Proposed device includes the electrosurgical probe (90-S Redesign) only. This premarket notification refers to the SERFAS 90-S Redesign unless Original SERFAS 90-S is stated.

Device Description

The Stryker SERFAS 90-S Electrosurgical Probe (hereafter referred to as "Proposed device") is an accessory to the SERFAS Energy System, marketed through K041810, which is intended for resection, ablation, and coagulation of soft tissue via radiofrequency (RF) ablation. RF ablation probes are the main tool used in most arthroscopic procedures for the removal of tissue and the coagulation of bleeding vessels. The Proposed device is a disposable single-use electrosurgical device provided sterile via Ethylene Oxide sterilization.

3. Indication for Use

The Stryker SERFAS 90-S electrosurgical probe is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic and arthroscopic procedures of joints such as the knee, shoulder, elbow, hip, ankle, and wrist.

4. Comparison of Technological Characteristics with the Predicate Device

The Stryker SERFAS 90-S electrosurgical probe and predicate device are similar in technological characteristics and design. The predicate device includes the entire SERFAS Energy system while the Proposed device includes the probe only.

The differences between the Proposed device and the predicate are minor and raise no new questions of safety and effectiveness, therefore supporting that the SERFAS 90-S electrosurgical probe is substantially equivalent to the predicate device currently on the market. The following differences exist between the Proposed and predicate device:

- Ceramic and Electrode Key Feature Design
- Electrode Face Suction Path
- Handle Design

<u>Ceramic and Electrode Key Feature Design</u>

Both the Proposed device and predicate device ceramic raw materials are identical but the devices have slightly different dimensional specifications. The intent of this change is to increase the mechanical robustness of the probe's tip and thereby address the failure mode of tip breakage. This difference is not critical to the intended surgical use of the device and does not impact the effectiveness of the device when used as labeled, however the safety of this product will be improved as a result of this change given the reduction in occurrence of tip breakage.

This minor difference in the Proposed device does not introduce additional risks and raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device.

Electrode Face Suction Path

The Proposed device contains minor electrode face suction path design differences compared to the predicate device. Both the Proposed device and predicate device electrode raw materials are identical but the devices have slightly different dimensional specifications.

This minor difference in the Proposed device does not introduce additional risks and raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device.

Handle Design

The patient contacting raw materials of the Proposed device and predicate device handle are identical. The Proposed device has a slightly different design specification for improved safety. This difference is not critical to the intended surgical use of the device and does not affect the effectiveness of the device when used as labeled, however the safety of this product will be improved as a result of this change because the occurrence of unintentional activation will be decreased.

This minor difference in the Proposed device does not introduce additional risks and raises no new questions of safety or effectiveness and is substantially equivalent to the predicate device.

5. Performance Testing

The Stryker SERFAS 90-S Electrosurgical probe was tested for performance in accordance with internal design specification and with the applicable performance standards, which established the substantial equivalence determination. The following non-clinical tests were conducted and are summarized in this premarket notification:

Test Name	Description	Results
Aggressive Use	Determines if a probe can last its full lifetime without failure while being subjected to an extended activation period on tissue at the highest power setting.	Pass
Tip Cantilever	Determines if the probe tip can withstand the normal, side, and back force required to permanently deform the lumen	Pass

Test Name	Description	Results
Electrode Bend	Verifies the electrode can withstand a 7lb force for a worst case scenario.	Pass
Thermal Expansion (Heat) Test	Verifies that the SERFAS probe tip assembly does not experience thermal expansion capable of causing catastrophic failure when subject to excessive heat	Pass
Leak	Verifies the condition of the ceramic-outer lumen assembly and the condition of the suction clamp of all styles of Stryker and non-Stryker RF ablation probes.	Pass
System Compatibility	Verifies that the electrosurgical probe is compatible with Stryker's legally marketed consoles	Pass

Biocompatibility was assessed in accordance with ISO 10993-1:2009 "Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing within a Risk Management Process" and related collateral standards for patient contacting materials (see Section 15 – Biocompatibility).

Sterilization was assessed in accordance with ISO 11135:2014 – Sterilization of health-care products - Ethylene Oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices. Sterilization residuals were assessed in accordance with ISO 10993-7 - Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (see Section 14 – Sterilization and Shelf Life).

Bench performance testing was conducted to ensure that the device functioned as intended and met design specifications and acceptance criteria. Test results obtained verified the safety and effectiveness of the device per design specifications and applicable standards (see Section 18 – Performance Testing – Bench).

6. Conclusion

Based on the intended use, technological characteristics, performance testing, and non-clinical testing in comparison to the predicate device, the Stryker SERFAS 90-S Electrosurgical Probe does not introduce additional risks and raises no new questions of safety and effectiveness, thus demonstrating substantial equivalence.