January 26, 2018

Stryker
Benjamin Krebs
Quality Engineer
5900 Optical Court
San Jose, California 95138

Re: K171391
Trade/Device Name: Stryker 90-S Max SERFAS Energy Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 9, 2017
Received: May 11, 2017

Dear Benjamin Krebs:

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,

Jennifer R. Stevenson -S3

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K171391

Device Name
Stryker SERFAS 90-S Max Electrosurgical Probe

Indications for Use *(Describe)*
The Stryker SERFAS 90-S Max 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.***

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*"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<br>San Jose, CA 95138 |
| **FDA Registration Number** | 2936485 |
| **Correspondence Person** | Mr. Benjamin Krebs<br>Quality Engineer<br>Stryker Corporation |
| **Contact Information** | Email: ben.krebs@stryker.com<br>Phone: (408) 754-2897<br>Fax: (408)-754-2969 |
| **Date Prepared** | January 25, 2018 |

## 2. Device Identification

**Proposed Device:**

| | |
|---|---|
| **Proprietary Name** | Stryker® SERFAS 90-S Max 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 |

**Primary Predicate Device:**

| | |
|---|---|
| **Proprietary Name** | Stryker® SERFAS 90-S Electrosurgical Probe |
| **Common Name** | RF Probe |
| **Premarket Notification** | K160050 |
| **Classification Name** | Electrosurgical Cutting and Coagulation Device and Accessories |
| **Regulation Number** | 21 CFR 878.4400 |
| **Product Code** | GEI |
| **Regulatory Class** | II |

**Reference Device:**

| | |
|---|---|
| **Proprietary Name** | SERFAS Energy System |
| **Common Name** | RF Probe |
| **Premarket Notification** | K041810 |
| **Classification Name** | Electrosurgical Cutting and Coagulation Device and Accessories |
| **Regulation Number** | 21 CFR 878.4400 |
| **Product Code** | GEI |
| **Regulatory Class** | II |

**Device Description**

The Stryker SERFAS 90-S Max electrosurgical probe (hereafter referred to as "Proposed device") is an accessory to the SERFAS Energy System, marketed through K041810 and K160050, and the Crossfire Arthroscopy System, marketed through K071859, 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. Indications for Use

The Stryker SERFAS 90-S Max 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 Max electrosurgical probe is similar to the predicate device with respect to technological characteristics and design. The modifications of the Proposed device, listed below, are minor and testing confirms that these modifications do not raise any new questions of safety or effectiveness, therefore supporting that the SERFAS 90-S Max electrosurgical probe is substantially equivalent to the predicate device currently on the market.

The following differences exist between the Proposed device and the predicate device:

- Probe Tip (Electrode and Ceramic) Design
- Outer Lumen Heat Shrink Material

## 5. Performance Testing

The Stryker SERFAS 90-S Max electrosurgical probe was tested for performance in accordance with internal design specifications and with the applicable performance standards, which established the substantial equivalence determination. The following non-clinical tests were conducted and are summarized in the table below:

| Test Name | Description | Results |
|---|---|---|
| Aggressive Use | Determines if a probe can last its full lifetime without failure | Pass |
| Tip Cantilever | Determines if the probe tip can withstand the normal and side force | Pass |
| Torsion in a Slot | Determines if the probe tip can withstand torsional forces | Pass |
| Bending Moment | Verifies failure mode while probe is used in prying manner | Pass |
| Impact | Determines a probe can survive an impact of a hard object | Pass |
| Electrode Pull | Determines the force at which the electrode is pulled out of the probe tip assembly | Pass |
| Heat | Determines if the probe tip can withstand extreme temperatures | Pass |
| Captured Tip | Determines strength of probe tip assembly | Pass |
| Leak | Determines if probe will allow leakage. | Pass |
| Heat Shrink Mechanical Force | Determines mechanical strength of heat shrink | Pass |
| Shaft Compression | Determines if the probe can withstand representative compressive force on shaft | Pass |
| Thermal Damage | Determines the thermal effect on tissue of the proposed device compared to the reference device. | Pass |

Bench performance testing was conducted to ensure that the device functioned as intended and met design specifications and acceptance criteria.

## 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 Max electrosurgical probe does not raise any new questions of safety and effectiveness, therefore demonstrating substantial equivalence.