



January 24, 2019

Stryker Sustainability Solutions  
Mia McCorkel  
Regulatory Affairs Specialist  
1810 W. Drake Drive  
Tempe, Arizona 85283

Re: K181056

Trade/Device Name: Reprocessed CS Diagnostic Electrophysiology Catheter  
Regulation Number: 21 CFR 870.1220  
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe  
Regulatory Class: Class II  
Product Code: NLH  
Dated: December 21, 2018  
Received: December 26, 2018

Dear Mia McCorkel:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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

Enclosure

The following device models are included in the scope of this 510(k) submission:

Model Number	Description
BD710DF282RTS	Bi-Directional Catheter, 7F, DF Curve, 115 cm useable length, 2 mm tip electrode
BD710FJ282RTS	Bi-Directional Catheter, 7F, FJ Curve, 115 cm useable length, 2 mm tip electrode
BD710DF282CT	Bi-Directional Catheter with Auto ID Technology, 7F, DF Curve, 115 cm useable length, 2 mm tip electrode
BD710FJ282CT	Bi-Directional Catheter with Auto ID Technology, 7F, FJ Curve, 115 cm useable length, 2 mm tip electrode

## Indications for Use

510(k) Number (if known)

K181056

Device Name

Reprocessed CS Diagnostic Electrophysiology Catheter

Indications for Use (Describe)

The Reprocessed CS Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.

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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## Change Being Effected – Addition of Contraindication

### 510(k) Summary

**SUBMITTER:**

Stryker Sustainability Solutions  
1810 W. Drake Drive  
Tempe, Arizona 85283

**CONTACT:**

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Date of Preparation: January 24, 2019

**NAME OF DEVICE:**

*Trade/Proprietary Name:* Reprocessed CS Diagnostic Electrophysiology Catheter  
*Model Numbers:* BD710DF282RTS, BD710DF282CT, BD710FJ282RTS, BD710FJ282CT  
*Common Name:* Electrode recording catheter or electrode recording probe  
*Classification Information:* Cardiovascular, Reprocessed (21 CFR §870.1220, Product Code NLH, Class II)

**PREDICATE DEVICES:**

<b>510(k) Number</b>	<b>510(k) Title</b>	<b>Original Manufacturer</b>
K100254	Reprocessed CS Bi-Directional Diagnostic Electrophysiology Catheter	Stryker Sustainability Solutions
K090898	Coronary Sinus Deflectable Mapping Catheters, Webster CS Catheter with EZ Steer Technology, Webster CS Catheter with EZ Steer Technology and Auto ID	Biosense Webster, Inc.
K101345	Webster CS Catheter with EZ Steer Technology, Webster CS Catheter with EZ Steer Technology an Auto ID	Biosense Webster, Inc.

**DEVICE DESCRIPTION:**

The Reprocessed CS Diagnostic Electrophysiology Catheter is a steerable, multi-electrode catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart. The device is a 7FR catheter with a usable length of 115 cm. The catheter has a high-torque shaft with a braided deflectable, Bi-Directional tip section containing platinum electrodes that can be used for recording and stimulation. Two curve types, D/F and F/J, for CS placement, are available.

Specific to Reprocessed CS Diagnostic Electrophysiology Catheters with Auto ID Technology: Each catheter is equipped with EEPROM (Electrically Erasable Programmable Read Only Memory), which is used to save unique catheter identification information. CARTO® EP Navigation Systems equipped with Auto ID Technology can access the saved information and automatically recognize the catheter information.

This device has been cleared for three (3) reprocessing cycles.

**INTENDED USE:**

The Reprocessed CS Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.

**COMPARISON WITH THE PREDICATE DEVICE:**

The only modification made was to the Instructions for Use. The following contraindications were added.

- Use of the catheter is contraindicated in patients with totally obstructed Coronary Sinus.
- The catheter should not be used in patients unable to receive heparin or an acceptable alternative to achieve the adequate anticoagulation.
- Electrophysiology studies are contraindicated when reversible factors make the findings unrepresentative of the patient's disease state (e.g. electrolyte imbalance).

**DEVICE MODEL NUMBERS:**

Original Manufacturer	Model Number	Description
Biosense Webster	BD710DF282RTS	Reprocessed CS Diagnostic Electrophysiology Catheter, 7F, DF Curve, 115 cm useable length, 2 mm tip electrode
Biosense Webster	BD710FJ282RTS	Reprocessed CS Diagnostic Electrophysiology Catheter, 7F, FJ Curve, 115 cm useable length, 2 mm tip electrode
Biosense Webster	BD710DF282CT	Reprocessed CS Diagnostic Electrophysiology Catheter with Auto ID Technology, 7F, DF Curve, 115 cm useable length, 2 mm tip electrode
Biosense Webster	BD710FJ282CT	Reprocessed CS Diagnostic Electrophysiology Catheter with Auto ID Technology, 7F, FJ Curve, 115 cm useable length, 2 mm tip electrode

**CONCLUSION:**

The Reprocessed CS Diagnostic Electrophysiology Catheters are safe, effective, and substantially equivalent to the predicate devices as described herein. The only modification made was to the Instructions for Use as described.