Edwards Lifesciences LLC
Ms. Rachel Libi
Vice President, Regulatory Affairs, TMTT
One Edwards Way
Irvine, California 92614

Re: Q230131
Trade/Device Name: PASCAL Stabilizer Rail System and Table
Evaluation of Accessory Classification Under Section 513(f)(6) - Accessory Classification Request
Regulation Number: 21 CFR 870.3955
Regulation Name: Cardiovascular Delivery Catheter System Positioning and Stabilization Device
Regulatory Classification: Class I
Product Code: QWA
Dated: January 18, 2023
Received: January 20, 2023

Dear Ms. Libi:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Accessory Classification Request for classification of the PASCAL Stabilizer Rail System and Table, a prescription device under 21 CFR 801.109 that is intended to aid the positioning and stabilization of the PASCAL Precision Implant System catheters during implantation procedures.

FDA concludes that this device should be classified into Class I. This order, therefore, classifies the PASCAL Stabilizer Rail System and Table, and substantially equivalent devices of this generic type, into Class I under the generic name Cardiovascular Delivery Catheter System Positioning and Stabilization Device.

FDA identifies this generic type of device as:

> **Cardiovascular Delivery Catheter System Positioning and Stabilization Device**. A cardiovascular delivery catheter system positioning and stabilization device is a platform device or a part of a platform device that aids the positioning and stabilization of delivery catheter systems during cardiovascular interventional procedures (e.g., transcatheter valvular interventions). The device only provides mechanical support and does not include any electrical or robotic components. The device may be for single use or reusable.

Section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was added by section 707 of

the FDA Reauthorization Act of 2017 (FDARA) on August 18, 2017 and was effective on October 17, 2017 (Pub. L. 115-52). This provision establishes a pathway for manufacturers or importers to request classification of accessories distinct from another device upon written request. The classification is based upon the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request proper classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days announcing the classification.

Alternatively, under section 513(f)(6)(C), a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days announcing the classification.

FDA received your Accessory Classification request on January 20, 2023 to classify the PASCAL Stabilizer Rail System and Table into Class I under section 513(f)(6)(D)(ii) of the FD&C Act. In order to classify the PASCAL Stabilizer Rail System and Table into Class I or II, the proposed class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the Accessory Classification request, FDA has determined that the PASCAL Stabilizer Rail System and Table intended for aiding the positioning and stabilization of the PASCAL Precision Implant System catheters during implantation procedures can be classified in Class I. FDA has determined that Class I (general controls) provide reasonable assurance of the safety and effectiveness of the device type.

FDA has identified the following risks to health associated specifically with this type of device: (1) procedural delays associated with the accessory not performing as intended dimensionally or functionally; and (2) systemic infection associated with compromise of the sterile field by a non-sterile component during a procedure or inadequate sterilization of a sterile component.

The Cardiovascular Delivery Catheter System Positioning and Stabilization Device is subject to the general controls of the FD&C Act. Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a Class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does not meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this

device need not submit a premarket notification containing information on the Cardiovascular Delivery Catheter System Positioning and Stabilization Device they intend to market prior to marketing the device subject to the limitations of exemptions found in Title 21 of the CFR in sections 862.9 through 892.9.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this Accessory Classification request does not mean that FDA has determined that your device complies with other requirements of the FD&C Act or any Federal statutes or regulations administered by other Federal agencies. You must comply with all applicable requirements under the FD&C Act, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and, if applicable, 809); 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order is on file in the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and is available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may market your device as described in the Accessory Classification request, provided that your device complies with the general control provisions of the FD&C Act.

Unique device identification (UDI) requirements apply broadly to all medical devices, unless an exception or alternative applies. Please note that because the UDI compliance dates are phased in over time based on device risk, and because the UDI regulations include some device class-specific provisions, this classification decision may impact your UDI implementation. For additional information, please visit our website at https://www.fda.gov/udi.

If you have any questions concerning this classification order, please contact Changfu Wu, Ph.D., at 301-796-6086 or Changfu.Wu@fda.hhs.gov.

Sincerely,

Bram Zuckerman, M.D.
Director
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health