February 5, 2024

Edwards Lifesciences
Peter Lindwall
Director, Regulatory Affairs
1 Edwards Way
Irvine, California 92614

Re: K233895
Trade/Device Name: EZ Glide Aortic Perfusion Cannulae (EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A and EZS24TA); OptiSite Arterial Perfusion Cannulae (OPTI16, OPTI18, OPTI20 and OPTI22); EndoReturn Arterial Cannulae (ER21B and ER23B);
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: December 7, 2023
Received: December 11, 2023

Dear Peter Lindwall:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233895

Device Name
OptiSite Arterial Perfusion Cannulae

Indications for Use *(Describe)*
OptiSite Arterial Perfusion Cannulae:

The Edwards Lifesciences arterial perfusion cannulae are indicated for arterial perfusion in the extracorporeal circuit for < 6 hours. Cannulation site selection is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233895

Device Name
EndoReturn Arterial Cannulae

Indications for Use *(Describe)*
EndoReturn Arterial Cannulae:

The EndoReturn arterial cannula are indicated for patients undergoing cardiopulmonary bypass. They are intended to deliver oxygenated blood for cardiopulmonary bypass during surgery.
The EndoReturn arterial cannula with hemostasis valve also allows the hemostatic introduction and removal of vascular catheters such as the EndoClamp aortic catheter.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233895

Device Name
EZ Glide Aortic Perfusion Cannulae

Indications for Use *(Describe)*
EZ Glide Aortic Perfusion Cannulae:

Aortic perfusion cannulae are intended for perfusion of the aorta during short-term (≤6 hours) cardiopulmonary bypass procedures.
Aortic perfusion cannulae may be used in pediatric or adult populations based on the flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

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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K233895 510(k) Summary, revised 01-30-2024

Contact Details	
Applicant Name	Edwards Lifesciences
Applicant Address	1 Edwards Way Irvine CA 92614 United States
Applicant Contact Telephone	949-701-8980
Applicant Contact	Mr. Peter Lindwall
Applicant Contact Email	peter_lindwall@edwards.com
Device Name	
Device Trade Name	EZ Glide Aortic Perfusion Cannulae (EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A and EZS24TA); OptiSite Arterial Perfusion Cannulae (OPTI16, OPTI18, OPTI20 and OPTI22); EndoReturn Arterial Cannulae (ER21B and ER23B)
Common Name	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Classification Name	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass
Regulation Number	870.4210
Product Code	DWF

Legally Marketed Predicate Devices		
Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K123370	EZ Glide Aortic Perfusion Cannulae	DWF
K073559	OptiSite Arterial Perfusion Cannulae	DWF
K971291	EndoReturn Arterial Cannulae	DWF

Device Description Summary

EZ Glide Aortic Perfusion Cannulae, General Description & Operation of Action
Note: There is no change to the general description or operation of the device from the predicate EZ Glide Aortic Perfusion Cannulae device. There is no change to the design or manufacturing of the device from the predicate EZ Glide Aortic Perfusion Cannulae Device.
The EZ Glide Aortic Perfusion Cannulae device deliver oxygenated blood from the cardiopulmonary bypass pump directly into the aorta. The cannulae terminate in a 3/8" (9.5mm) barbed tubing connector and a vent plug. Cannulae are wire-reinforced and include a dispersion tip in either a straight or curved configuration. EZ Glide Aortic Cannulae are available in sizes 21 French (Fr) and 24 French (Fr). The EZ Glide Aortic Cannulae are packaged sterile and non-pyrogenic in a sealed, peel-type pouch. Note that there are **no** accessories packaged with the EZ Glide Aortic Perfusion Cannulae.

OptiSite Arterial Perfusion Cannulae, General Description & Operation of Action
Note: There is no change to the general description or operation of the device from the predicate OptiSite Arterial Perfusion Cannulae device. There is no change to the design or manufacturing of the device from the predicate OptiSite Arterial Perfusion Cannulae Device.

The OptiSite Arterial Perfusion Cannulae device is indicated for arterial perfusion in the extracorporeal circuit for less than 6 hours. Cannulation site selection is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.
The Edwards Lifesciences Arterial Perfusion Cannulae have smoothly rounded tips to facilitate atraumatic insertion. The proximal ends of the cannula are designed to accept 3/8" (9.5mm) tubing.
Introducers are provided with some arterial cannula codes. Introducers are designed for use with 0.038" (0.96 mm) guidewires. Each introducer is provided with a removable vented luer cap. Leave the vented cap in place to allow venting of the cannula for use without a guidewire. Remove the cap to allow cannula use with a guidewire. The OptiSite Arterial Perfusion Cannulae are packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

EndoReturn Arterial Cannulae, General Description & Operation of Action
Note: There is no change to the general description or operation of the device from the predicate EndoReturn Arterial Cannulae device. There is no change to the design or manufacturing of the device from the predicate EndoReturn Arterial Cannulae Device.
The EndoReturn Arterial Cannulae devices are flexible plastic tubes intended to provide a means of perfusing arterial blood returning to the patient from the oxygenator through the extracorporeal circuit during cardiopulmonary bypass procedures. The cannulae are placed either through the femoral artery or directly into the aorta to return oxygenated blood from the CPB circuit and to hemostatically introduce Edwards intra-aortic occlusion catheters. Each device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch and are intended and labeled for single use only.
The Endo Return Arterial Cannulae with the hemostasis valve are made with a wire-reinforced cannula shaft which provides kink resistance and flexibility, and include the following kit components:

- Introducer
- Guidewire (0.038" (0.097mm) x 100 cm) J-tip
- Connector hub

The tapered atraumatic tip aids in insertion and advancement into the femoral artery. The non-wire-reinforced clamp site(s), a 3/8 in. barbed connector, and a hemostasis valve allows passage of catheters such as the Edwards IntraClude intra-aortic occlusion device. The introducers accept a 0.038 in. (0.97 mm) guidewire and are marked to simplify assembly. A connector hub secures and immobilizes the introducer within the cannula for easier, one-person insertion of the cannula/introducer assembly. A lubricious coating, (SlipCoat™) is applied to the surface of the EndoReturn arterial cannula shafts. This coating is intended to provide a lubricious surface effective for the duration of the intended use of the cannula, thereby easing the insertion of the cannula into the artery, and the aortic occlusion catheters through the cannula. The EndoReturn Arterial Cannulae are packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

Intended Use/Indications for Use

EZ Glide Aortic Perfusion Cannulae:
Aortic perfusion cannulae are intended for perfusion of the aorta during short-term (≤6 hours) cardiopulmonary bypass procedures.
Aortic perfusion cannulae may be used in pediatric or adult populations based on the flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

OptiSite Arterial Perfusion Cannulae:
The Edwards Lifesciences arterial perfusion cannulae are indicated for arterial perfusion in the extracorporeal circuit for < 6 hours. Cannulation site selection is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.

EndoReturn Arterial Cannulae:
The EndoReturn arterial cannula are indicated for patients undergoing cardiopulmonary bypass. They are intended to deliver oxygenated blood for cardiopulmonary bypass during surgery.
The EndoReturn arterial cannula with hemostasis valve also allows the hemostatic introduction and removal of vascular catheters such as the EndoClamp aortic catheter.

Indications for Use Comparison

Predicate and Substantial Equivalence Device Information, Indications for Use comparison,
EZ Glide Aortic Perfusion Cannulae
The subject EZ Glide Aortic Perfusion Cannulae is substantially equivalent to the EZ Glide Aortic Perfusion Cannulae device cleared in in K123370 on March 13, 2013. There is no substantial change to Indications for Use, since Edwards no longer manufacture cannulae with the Duraflo coating, no change in design and no change in manufacturing between the predicate and subject device.

Predicate device Indications for Use:
Aortic perfusion cannulae are intended for perfusion of the aorta during short-term (≤6 hours) cardiopulmonary bypass procedures.
Aortic perfusion cannulae may be used in pediatric or adult populations based on the flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.
Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Subject device Indications for Use:
Aortic perfusion cannulae are intended for perfusion of the aorta during short-term (≤6 hours) cardiopulmonary bypass procedures.
Aortic perfusion cannulae may be used in pediatric or adult populations based on the flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

Predicate and Substantial Equivalence Device Information, Indications for Use comparison,
OptiSite Arterial Perfusion Cannulae
The subject OptiSite Arterial Perfusion Cannuale is substantially equivalent to the OptiSite Arterial Perfusion Cannulae device cleared in K073559 on January 24, 2008. There is no substantial change to Indications for Use, no change in design and no change in manufacturing between the predicate and subject device.

Predicate device Indications for Use:
The Edwards Lifesciences Arterial Perfusion Cannula is indicated for arterial perfusion in the extracorporeal circuit for <6 hours.
Cannulation site selection is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.

Subject device Indications for Use:
The Edwards Lifesciences arterial perfusion cannulae are indicated for arterial perfusion in the extracorporeal circuit for < 6 hours.
Cannulation site selection is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.

Predicate and Substantial Equivalence Device Information, Indications for Use comparison, **EndoReturn Arterial Cannulae**
The subject EndoReturn Arterial Cannulae is substantially equivalent to the EndoReturn Arterial Cannulae device cleared in K971291 on June 17, 1997. There is no substantial change to Indications for Use, no change in design and no change in manufacturing between the predicate and subject device.

Predicate device Indications for Use:
The Endoarterial Return Cannula, with or without hemostasis valve, is indicated for patients undergoing cardiopulmonary bypass. It is intended to deliver oxygenated blood for cardiopulmonary bypass during surgery.

The Endoarterial Return Cannula with hemostasis valve also allows the hemostatic introduction and removal of vascular catheters such as the Heartport™ Endoaortic Clamp™ Catheter.

Subject device Indications for Use:
The EndoReturn arterial cannula are indicated for patients undergoing cardiopulmonary bypass. They are intended to deliver oxygenated blood for cardiopulmonary bypass during surgery.
The EndoReturn arterial cannula with hemostasis valve also allows the hemostatic introduction and removal of vascular catheters such as the EndoClamp aortic catheter.

Technological Comparison

Predicate and Substantial Equivalence Device Information, **EZ Glide Aortic Perfusion Cannulae**
The subject EZ Glide Aortic Perfusion Cannulae is substantially equivalent to the EZ Glide Aortic Perfusion Cannulae device cleared in in K123370 on March 13, 2013. There is no change to Indications for Use, no change in design and no change in manufacturing between the predicate and subject device.
The following description applies to both the predicate and subject device:
The EZ Glide Aortic Perfusion Cannulae device deliver oxygenated blood from the cardiopulmonary bypass pump directly into the aorta. The cannulae terminate in a 3/8" (9.5mm) barbed tubing connector and a vent plug. Cannulae are wire-reinforced and include a dispersion tip in either a straight or curved configuration. EZ Glide Aortic Cannulae are available in sizes 21 French (Fr) and 24 French (Fr). The EZ Glide Aortic Cannulae are packaged sterile and non-pyrogenic in a sealed, peel-type pouch. Note that there are no accessories packaged with the EZ Glide Aortic Perfusion Cannulae.
The subject and predicate EZ Glide Aortic Perfusion Cannulae are substantially equivalent with respect to the following characteristics as there are no changes to the:
• Intended use•

• Patient population
• Fundamental scientific technology
• Operating principle
• Performance specifications
- Design
- Manufacturing

Change description: The EZ Glide Aortic Perfusion Cannulae will be updated via an insert addendum with the following new warning statement:

Use the depth marks to position the cannula in the desired location within the aorta. Placement of the cannula too distally in the central aorta can lead to cerebral hypoperfusion, severe ischemic injury, and/or death.

Predicate and Substantial Equivalence Device Information, **OptiSite Arterial Perfusion Cannulae**

The subject OptiSite Arterial Perfusion Cannuale is substantially equivalent to the OptiSite Arterial Perfusion Cannulae device cleared in K073559 on January 24, 2008. There is no change in design and no change in manufacturing between the predicate and subject device. The following description applies to both the predicate and subject device:

The OptiSite Arterial Perfusion Cannulae device is indicated for arterial perfusion in the extracorporeal circuit for less than 6 hours. Cannulation site selection is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.

The Edwards Lifesciences Arterial Perfusion Cannulae have smoothly rounded tips to facilitate atraumatic insertion. The proximal ends of the cannula are designed to accept 3/8" (9.5mm) tubing.

Introducers are provided with some arterial cannula codes. Introducers are designed for use with 0.038" (0.96 mm) guidewires. Each introducer is provided with a removable vented luer cap. Leave the vented cap in place to allow venting of the cannula for use without a guidewire. Remove the cap to allow cannula use with a guidewire. The OptiSite Arterial Perfusion Cannulae are packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

The subject and predicate OptiSite Arterial Perfusion Cannulae are substantially equivalent with respect to the following characteristics as there are no changes to the:

• Intended use•
• Patient population
• Fundamental scientific technology
• Operating principle
• Performance specifications
- Design
- Manufacturing

Change description:

A) The OptiSite Arterial Perfusion Cannulae will be updated via an insert addendum with the following new warning statement:
Use the depth marks to position the cannula in the desired location. Improper placement of the cannula can lead to severe ischemic injury, and/or death.

B) The OptiSite Arterial Perfusion Cannulae IFU will be updated to remove any references to the Duraflo heparin treatment.

Predicate and Substantial Equivalence Device Information, **EndoReturn Arterial Cannulae**
The subject EndoReturn Arterial Cannulae is substantially equivalent to the EndoReturn Arterial Cannulae device cleared in K971291 on June 17, 1997. There is no change to Indications for Use, no change in design and no change in manufacturing between the predicate and subject device.
The following description applies to both the predicate and subject device:
The EndoReturn Arterial Cannulae devices are flexible plastic tubes intended to provide a means of perfusing arterial blood returning to the patient from the oxygenator through the extracorporeal circuit during cardiopulmonary bypass procedures. The cannulae are placed either through the femoral artery or directly into the aorta to return oxygenated blood from the CPB circuit and to hemostatically introduce Edwards intra-aortic occlusion catheters. Each device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch and are intended and labeled for single use only.
The Endo Return Arterial Cannulae with the hemostasis valve are made with a wire-reinforced cannula shaft which provides kink resistance and flexibility, and include the following kit components:
• Introducer
• Guidewire (0.038" (0.097mm) x 100 cm) J-tip
• Connector hub
The tapered atraumatic tip aids in insertion and advancement into the femoral artery. The non-wire-reinforced clamp site(s), a 3/8 in. barbed connector, and a hemostasis valve allows passage of catheters such as the Edwards IntraClude intra-aortic occlusion device. The introducers accept a 0.038 in. (0.97 mm) guidewire and are marked to simplify assembly. A connector hub secures and immobilizes the introducer within the cannula for easier, one-person insertion of the cannula/introducer assembly. A lubricious coating, (SlipCoat™) is applied to the surface of the EndoReturn arterial cannula shafts. This coating is intended to provide a lubricious surface effective for the duration of the intended use of the cannula, thereby easing the insertion of the cannula into the artery, and the aortic occlusion catheters through the cannula. The EndoReturn Arterial Cannulae are packaged sterile and non-pyrogenic in a sealed, peel-type pouch.
The subject and predicate EndoReturn Arterial Cannulae are substantially equivalent with respect to the following characteristics as there are no changes to the:
• Intended use•
• Patient population
• Fundamental scientific technology
• Operating principle
• Performance specifications
- Design
- Manufacturing

Change description: The EndoReturn Arterial Cannulae will be updated via an insert addendum with the following new warning statement:

Use the depth marks to position the cannula in the desired location. Improper placement of the cannula can lead to severe ischemic injury, and/or death.

Non-Clinical and/or Clinical Tests Summary & Conclusions

No Non-Clinical and/or Clinical Tests were carried out in support of this special 510(k) premarket notification.