June 17, 2026

Portal Access, Inc.
Hila Ravid
VP QA&RA
4201 Collins Ave.
Apt. 601
Miami Beach, Florida 33140

Re: K260916
Trade/Device Name: FLEXI-PORT™ Power Injectable Implantable Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, implanted, intravascular infusion port and catheter
Regulatory Class: Class II
Product Code: LJT
Dated: March 19, 2026
Received: March 19, 2026

Dear Hila Ravid:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

DAVID WOLLOSCHECK -S

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260916

Device Name
FLEXI-PORT™ Power Injectable Implantable Port

Indications for Use *(Describe)*
The FLEXI-PORT Power Injectable Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications including anti-cancer medications (chemotherapy), I.V. fluids, parenteral nutrition solutions, blood products, and for withdrawal of blood samples.

When used with a power injectable needle, the FLEXI-PORT is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

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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510K SUMMARY

Traditional Premarket Notification Submission – 510(k)

Portal Access Inc - FLEXI-PORT™ Power Injectable Implantable Port

510(k) Number K260916

Date Prepared: June 17, 2026

1. Submitter

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2. Contact Person

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3. Device

Trade Name: FLEXI-PORT™ Power Injectable Implantable Port
Common or Usual Name: Subcutaneous Implanted Intravascular Port & Catheter
Classification Name: 21 CFR 880.5965 - Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Classification Panel: General Hospital
Product Code: LJT

4. Predicate Device

510(k) Number: K242328
Trade Name: Bard Access Systems, Inc., PowerPort™ ClearVUE™ Slim Implantable Port
Common or Usual Name: Subcutaneous Implanted Intravascular Port & Catheter
Classification Name: 21 CFR 880.5965 - Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Classification Panel: General Hospital
Product Code: LJT

5. Device Description

The FLEXI-PORT is a totally implantable vascular access device designed to provide repeated access to a patient's vascular system.

The FLEXI-PORT device consists of two primary components:

(i) a radiopaque injection port with a self-sealing silicone septum and titanium stem (Port);

(ii) a radiopaque single-lumen catheter (Catheter).
The port-catheter connection is secured by a radiopaque catheter connection lock (Cathlock).

The ports are available with either a 5 Fr or 6 Fr single-lumen catheter. The catheter may be pre-attached by the manufacturer or attached to the port by the practitioner during the implantation procedure.

The FLEXI-PORT is supplied as a sterile, single-use, non-pyrogenic kit containing the implantable port, catheter, and associated procedural accessories required to facilitate implantation. The kit is sterilized using a validated ethylene oxide (EtO) process to achieve a sterility assurance level (SAL) of 10^{-6}.

The port reservoir is accessed percutaneously using a non-coring (Huber) needle inserted through the self-sealing septum. Fluids, including medications, intravenous solutions, blood products, parenteral nutrition and contrast media, are delivered through the port and catheter into the central venous circulation. Power injection of contrast media is performed using a power injectable needle, and the device can be identified as power injectable under radiographic imaging by its radiopaque marker. Upon needle removal, the septum reseals, maintaining a closed, sterile fluid pathway.

6. Indications For Use

The FLEXI-PORT Power Injectable Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications including anti-cancer medications (chemotherapy), I.V. fluids, parenteral nutrition solutions, blood products, and for withdrawal of blood samples.

When used with a power injectable needle, the FLEXI-PORT is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

7. Comparison Of Technological Characteristics with the Predicate Device

A substantial equivalence table, which summarizes the similarities and differences between the FLEXI-PORT, and the predicate device, is provided below.

Specification	Subject Device FLEXI-PORT™ Power Injectable Implantable Port	Predicate Device PowerPort™ ClearVUE™ Slim Implantable Port	SE Justification
Device Identification			
510K Number	K260916	K242328	N/A
Manufacturer	Portal Access Inc.	Bard Access Systems Inc.	N/A
Device Classification Name	Port & Catheter, Implanted, Subcutaneous, Intravascular	Port & Catheter, Implanted, Subcutaneous, Intravascular	Same
Regulation Number	21 CFR §880.5965	21 CFR §880.5965	Same
Product Code	LJT	LJT	Same
Classification	Class II	Class II	Same

Specification	Subject Device FLEXI-PORT™ Power Injectable Implantable Port	Predicate Device PowerPort™ ClearVUE™ Slim Implantable Port	SE Justification
Device Use			
Intended Use	The FLEXI-PORT™ Power Injectable Implantable Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system	The PowerPort™ Implanted Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system	Same
Indications for Use	The FLEXI-PORT™ Power Injectable Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications including anti-cancer medications (chemotherapy), I.V. fluids, parenteral nutrition solutions, blood products, and for withdrawal of blood samples. When used with a power injectable needle, the FLEXI-PORT™ is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.	The PowerPort™ Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications including anti-cancer medicines (chemotherapy), I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with the PowerLoc™ Safety Infusion Set, the PowerPort™ Implantable Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.	SE – Similar indications for use. Difference in accessory labeling for power injection (power injectable needle vs. specific branded infusion set). This difference does not alter the intended use or clinical function and does not raise new questions of safety or effectiveness.
Patient Population	Patients requiring repeated access to the vascular system	Patients requiring repeated access to the vascular system	Same
Duration of Use	Long term (>30 days)	Long term (>30 days)	Same
Principles of Operation	The device operates as a totally implantable vascular access port consisting of a subcutaneous port with a self-sealing silicone septum connected to an intravascular catheter. The port is accessed percutaneously using a non-coring needle, allowing fluids to be delivered into the vascular system through the catheter.	The device operates as a totally implantable vascular access port consisting of a subcutaneous port with a self-sealing silicone septum connected to an intravascular catheter. The port is accessed percutaneously using a non-coring needle, allowing fluids to be delivered into the vascular system through the catheter.	Same
Insertion Site	Chest or Upper arm	Chest or Upper arm	Same
Visualization Techniques	Fluoroscopy	Fluoroscopy	Same

Specification	Subject Device FLEXI-PORT™ Power Injectable Implantable Port	Predicate Device PowerPort™ ClearVUE™ Slim Implantable Port	SE Justification
Catheter Tip Termination Location	Central venous system – lower 1/3 of superior vena cava preferred	Central venous system – lower 1/3 of superior vena cava preferred	Same
Design Characteristics			
Device Dimensions	Port: Septum length: 12.2 mm Septum width: 7.2 mm Septum surface area: 0.74 cm2 Height: 10.5 mm Width: 21.7 mm Length: 31 mm Reservoir Volume: 0.4 mL	Port: Septum diameter: 10.5 mm Septum surface area: 0.86 cm2 Height: 10.4 mm Width: 21.6 mm Length: 25.5 mm Reservoir Volume: 0.4 mL	SE – Differences in port dimensions. These differences do not affect device function. Performance testing demonstrated no new questions of safety or effectiveness.
	Catheter: 6 Fr x 46 cm 5 Fr x 51 cm	Catheter: 8 Fr x 46.4 cm 6 Fr x 46.4 cm	SE – Different catheter dimensions. These differences do not alter intended use, principle of operation, or clinical function. Performance testing demonstrated no new questions of safety or effectiveness.
Device Geometry & Materials	Port: - Rhombus Silicone overmolded hard plastic Radiopaque barium sulfate PEEK port top and base, including titanium stem and grasping tab - One-piece oval silicone septum - Radiopaque bismuth trioxide (Bi2O3)/Delrin CT symbol captured between the top and base assembly	Port: - Triangular hard plastic PEEK port cap and base, including stem - One-piece round silicone septum with 3 raised palpation bumps - 3 suture holes with or without silicone suture plugs - Radiopaque bismuth trioxide (Bi2O3)/Delrin CT symbol captured between the cap and base assembly	SE – Differences in port geometry and materials. These differences do not alter device function. Biocompatibility and performance testing demonstrated no new questions of safety or effectiveness.
	Catheter: Radiopaque Polyurethane tube Depth marking	Catheter: Radiopaque Polyurethane tube Depth marking	Same
	Cathlock: Radiopaque PEEK with laser marking locking collar	Cathlock: Polycarbonate with radiopaque print locking collar	SE – different materials. Same locking mechanism and function. Successful biocompatibility and performance testing demonstrated no new questions of safety or effectiveness.
Port Configuration	Single lumen port	Single lumen port	Same
Catheter Connection	Locking collar mechanism	Locking collar mechanism	Same

Specification	Subject Device FLEXI-PORT™ Power Injectable Implantable Port	Predicate Device PowerPort™ ClearVUE™ Slim Implantable Port	SE Justification
Maximum Pressure of Power Injectors' Setting	300 psi	300 psi	Same
Maximum Power Injection Flowrate	19/20 G needle = 5 mL/sec 22 G needle = 2 mL/sec	19/20 G needle = 5 mL/sec 22 G needle = 2 mL/sec	Same
Biocompatibility	ISO 10993-1	ISO 10993-1	Same
MR Compatibility	MR Conditional	MR Safe	SE – Different MR labeling classification. MR safety evaluation and labeling demonstrated no new questions of safety or effectiveness.
Sterilization	Sterilized by EtO, SAL 10^{-6}	Sterilized by EtO, SAL 10^{-6}	Same
Shelf Life	Shelf life for this device was established by evaluating the performance of port systems and packaging after accelerated or real time aging for 1 year	Shelf life for this device was established by evaluating the performance of port systems and packaging after accelerated or real time aging for 2 years	SE – Different labeled shelf life. Aging and performance testing demonstrated no new questions of safety or effectiveness.
Packaging	This device is packaged as a convenience kit in a blister tray covered with tray insert and sealed with Tyvek lid.	Triple tray packaging; two sterile barriers in the form of nested, sealed trays	SE – Different packaging configurations. Packaging validation demonstrated maintenance of the sterile barrier and no new questions of safety or effectiveness.

8. Non-Clinical Performance Testing

Comprehensive non-clinical performance testing was conducted to evaluate the safety and performance of the FLEXI-PORT device and to demonstrate substantial equivalence to the predicate device. Testing was performed in accordance with applicable FDA guidance documents and recognized international standards:

- FDA's Guidance on 510(k) Submissions for Implanted Infusion Ports, October 1990
- FDA's Guidance on Premarket Notification 510(K) Submission for Short-Term and Long-Term Intravascular Catheters, March 1995
- ISO 10555-6:2015 AMD 2019, Intravascular catheters – Sterile and single-use catheters – Part 6: Subcutaneous Implanted Ports
- ISO 10555-1:2023, Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements

8.1. Performance Bench Testing

The proposed FLEXI-PORT device successfully passed relevant testing per the above Guidance, standards, and pre-established acceptance criteria and internal product specification requirements, including:

- Port System Air Leak
- Port System Tensile
- Port System Static Burst Pressure
- Power injection Performance Testing

- Septum Performance (Durability and Puncture Life)
- Catheter Air Leak
- Catheter Tensile
- Catheter Collapse
- Catheter Kink
- Catheter Static Burst Pressure
- Catheter Hydratability
- Gravity Flow Rate
- Flushing Volume
- Priming Volume
- Tunneler-Catheter Tensile
- Simulated Use and Accessory Compatibility Testing
- Radiopacity
- Visual & Dimensional
- Corrosion Resistance
- MR Compatibility Testing (ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119); MR labeling established in accordance with ASTM F2503

All testing met predefined acceptance criteria. The results demonstrate that the subject device performs as intended and is substantially equivalent in safety and performance to the predicate device.

8.2. **Biocompatibility**

Biocompatibility testing for the proposed FLEXI-PORT device was performed in accordance with the FDA Guidance document "Use of International Standard ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The following tests were performed on ports which were Ethylene Oxide (EtO) sterilized,

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Muscle Implantation
- Subacute Toxicity
- Subchronic Toxicity
- Chronic Toxicity
- Genotoxicity (Bacterial Reverse Mutation Study, Mouse Lymphoma Assay)
- Hemocompatibility (Hemolysis - Extract and Direct Contact Method, Complement Activation, Partial Thromboplastic Time, Heparinized Blood Platelet and Leukocyte Count Assay)
- Particulate Analysis - Light Obscuration Method

In addition, Biological Risk Assessment was performed.

The overall biological safety profile supports that the FLEXI-PORT device is biocompatible for its intended use.

8.3. **Sterilization, Packaging and Shelf Life Testing**

The sterilization validation process conforms to ISO 11135:2014 Sterilization of health care products-Ethylene Oxide-Requirements for development, validation and routine control of a sterilization process for medical devices. The sterility assurance level (SAL) for the proposed device is $1x10^{-6}$. In addition, shelf life

and packaging testing were performed to support the labeled shelf life. All tests, including packaging integrity and device performance, were performed after environmental conditioning and distribution simulation.

Based on the completed sterilization validation, packaging qualification, and shelf-life testing, the FLEXI-PORT device has been demonstrated to maintain sterility, packaging integrity, and functional performance throughout the labeled shelf life.

9. Conclusion

Based on the intended use, technological characteristics, and performance data, the FLEXI-PORT Power Injectable Implantable Port is substantially equivalent to the identified predicate device.