April 29, 2026

Echo Medical, LLC
% Anna Landon
QA/RA Consultant
Landon Consulting, LLC
20451 Whitetree Cir
Huntington Beach, California 92646

Re: K260606
Trade/Device Name: Echo Large Bore Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 24, 2026
Received: February 24, 2026

Dear Anna Landon:

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,

FINN E. DONALDSON -S

Digitally signed by FINN E. DONALDSON -S
Date: 2026.04.29 10:49:47 -04'00'

For
Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260606

Device Name
Echo Large Bore Introducer Sheath

Indications for Use *(Describe)*
The Echo Large Bore Introducer Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

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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510(k) Summary

Echo Large Bore Introducer Sheath

Submitter

510 (k) Owner	Echo Medical LLC 9 Executive Circle, Suite 290 Irvine, CA, 92614
Primary Contact	Anna Landon +1 619-647-1050 QA/RA Consultant
Date Prepared	February 23, 2026

Device

Device Name	Echo Large Bore Introducer Sheath
Common Name	Large Bore Introducer Sheath
Classification Name	Catheter, Introducer (870.1340)
Product Code	DYB
Device Regulatory Class	Class 2

Predicate Device

Device Name	Gore DrySeal Flex Introducer Sheath
Premarket Notification Number	K160254

Device Description

The Echo Large Bore Introducer Sheath consists of an introducer sheath with attached hemostatic valve and a twist style locking dilator. The introducer sheath is comprised of a hydrophilic, coil-reinforced catheter that is attached to a rigid seal housing containing the hemostatic valve. The sheath includes a radiopaque marker band incorporated within the sheath material to allow identification under fluoroscopy. The hemostatic valve enables introduction of wires and catheters through the valve simultaneously with minimal blood loss. The valve is pressurized by injecting saline with a luer lock syringe during procedural preparation of the device. The valve housing contains a visual indicator to indicate the level of sealing pressure and also includes a suture loop on the distal end of the housing to secure it to the patient.

The dilator is radiopaque and has a tapered, flexible tip that facilitates atraumatic tracking through the vasculature and features which allow it to be locked into the sheath valve. The trailing end of the dilator has an adjustment clamp that aligns a groove near the dilator's tapered tip with the end of the sheath. This ensures a smooth, continuous transition between the dilator and the sheath.

The sheath shaft and the trailing end of the dilator shaft are marked with the French size to ensure correct combination of the dilator within the sheath.

Indications for Use

The Echo Large Bore Introducer Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

Comparison of Technological Characteristics with the Predicate Device

The proposed Echo Large Bore Introducer Sheath is comparable to the currently marketed Gore DrySeal Flex Introducer Sheath (K160254) with the following changes proposed in this submission:

- General Components – The subject device does not provide a syringe for device inflation. A standard 10mL off-the-shelf syringe is required for device preparation. Additionally, a 3-way stopcock is used for sheath flushing on the subject device.
- Radiopacity – The subject device dilator contains barium sulfate to enhance radiopacity.
- Sheath/Dilator Alignment – The subject device has a shallow groove in the dilator near the distal end that mates with the tip of the sheath to create a smooth transition between the dilator and sheath. An adjustment mechanism with a locking lever on the proximal end of the dilator is used to align the dilator groove under the sheath tip and then secure in place.
- Seal Inflation Mechanism and Indicator – The subject device includes an indicator to reflects the valve seal inflation pressure.

The indications for use, range of sheath diameters and lengths, principle of operation, and sterilization method remain identical to the predicate device. The proposed design has the same basic design, similar materials and similar device features.

Substantial Equivalence Summary		
Characteristic	Gore DrySeal Flex Introducer Sheath (K160254)	Echo Large Bore Introducer Sheath (Subject of this Submission)
Product Code and Regulation	Product Code DYB, Regulation 870.1340	Same as predicate
Intended Use / Indications for Use	The Gore DrySeal Flex Introducer Sheath is intended to be inserted in the vasculature to provide a	Same as predicate

Substantial Equivalence Summary		
Characteristic	Gore DrySeal Flex Introducer Sheath (K160254)	Echo Large Bore Introducer Sheath (Subject of this Submission)
	conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.	
Sizes (French and Length)	10-26Fr with lengths from 33cm – 65cm	Same as predicate
Single Use / Reusable	Single Use	Same as predicate
Coating	Hydrophilic Coating	Same as predicate
General System Components	A sheath consisting of hub with hemostasis valve, extension tube with stopcock, a twist style locking dilator, and a syringe.	The Echo device has the same general system components but does not include a syringe. The Echo device requires a standard off-the-shelf syringe.
Radiopacity	Radiopaque marker band incorporated within the sheath material to allow identification under fluoroscopy.	Similarly, the Echo device also contains a radiopaque marker band incorporated within the sheath material to allow identification under fluoroscopy. The Echo dilator contains barium sulfate to allow identification under fluoroscopy.
Guidewire Compatibility	0.035”	Same as predicate
Sheath/Dilator Interface	Dilator is locked onto the introducer sheath valve by rotating arrow to the lock / unlock icons on the sheath hub.	Same dilator locking as predicate. The Echo device also includes a dilator alignment step to mate the groove in the dilator with the tip of the sheath to create a smooth transition between the dilator and sheath.
Seal Inflation Mechanism and Indicator	Seal is inflated with saline by connecting a 2.5mL syringe (provided in packaging) to the port labeled “Valve”	Seal is inflated with saline by connecting a standard off-the-shelf syringe to the port labeled “Valve” The Echo device also includes a visual indicator which reflects sealing pressure.
Contraindications	No known contraindications	Same as predicate
Energy Source	None	Same as predicate
Sterilization Method	Ethylene Oxide	Same as predicate
Duration of Contact	≤ 24 hours (blood contact)	Same as predicate

Performance Data

The following performance data have been provided in support of substantial equivalence determination:

Bench Testing:

The following bench tests were conducted to support substantial equivalence to the predicate device:

- Dimensional
- Simulated Use through a Tortuous Model
- Kink Resistance
- Peak Tensile Force
- System Freedom from Leakage
- Lubricity
- Sheath Tip to Dilator Transition
- Dilator Removal Force
- Seal Durability Testing
- Seal Burst Testing
- Particulate
- Radiodetectability
- Sheath Luer Testing
- Human Factors / Usability Testing
- Packaging Validation
- Shelf Life

Sterilization Testing

The Echo Large Bore Introducer Sheath has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135 "*Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices"*.

Biocompatibility Evaluation

Biocompatibility testing was performed and meets the requirements of ISO 10993-1 *"Biological Evaluation of Medical Device – Part 1: Requirements and General Principles for the Evaluation of Biological Safety within a Risk Management Process"*

The following biocompatibility tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Pyrogenicity
- Systemic Toxicity
- Hemocompatibility
    - Hemolysis
    - Complement Activation
    - Platelet and Leukocyte
    - Partial Thromboplastin Time
    - Thrombogenicity

Animal Testing / Clinical Studies

No animal testing or clinical studies were performed.

Conclusion

The subject Echo Large Bore Introducer Sheath is substantially equivalent to the predicate GORE DrySeal Flex Introducer in terms of indications for use, design, materials, biocompatibility, packaging, sterilization, labeling, and performance.