January 22, 2026

Cultiv8 1, LLC
Robert Atkinson
CEO & Managing Director
3405 Annapolis Ln N
Suite 200
Plymouth, Minnesota 55447

Re: K253652
Trade/Device Name: Genie MAX Large Bore Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 14, 2025
Received: November 20, 2025

Dear Robert Atkinson:

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.

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: 2026.01.22 14:48:10 -05'00'

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)*
K253652

Device Name
Genie max large bore introducer sheath

Indications for Use *(Describe)*
The Cultiv8 Genie MAX is intended to be inserted into the vasculature to provide a conduit for introducing intravascular devices while providing a hemostatic seal to minimize blood loss.

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

# Genie MAX Large Bore Introducer Sheath

Prepared November 14, 2025

## Submitter


| Manufacturer: | Contact Person: |
|---|---|
| Cultiv8 1, LLC<br>3405 Annapolis Ln N, STE 200<br>Plymouth MN 55447 | Robert Atkinson<br>bob@cultiv8medical.com<br>612-226-6874 |


## Device

| | |
|---|---|
| Device Name: | Genie MAX Large Bore Introducer Sheath |
| Common / Usual Name: | Large Bore Introducer Sheath |
| Classification Name: | Catheter Introducer (21 CFR 870.1340) |
| Product Code | Introducer, Catheter (DYB) |
| Device Regulatory Class: | Class 2 |

## Predicate

| | |
|---|---|
| Device Name: | GORE DrySeal Flex Introducer Sheath |
| Premarket Notification Number: | K160254 |

## Device Description

The Genie MAX is a large bore introducer sheath system used for providing a conduit for introduction of intravascular devices while providing a hemostatic seal. The system includes an introducer sheath, protector, dilator and a 3cc syringe.

## Indications for Use

The Cultiv8 Genie MAX is intended to be inserted into the vasculature to provide a conduit for introducing intravascular devices while providing a hemostatic seal to minimize blood loss.

## Comparison of Technological Characteristics with the Predicate Device

The Genie MAX and the proposed predicate device have the same intended use and medical device classification information. The Genie MAX construction and materials are similar to the predicate device. The construction of the Genie MAX and the predicate device both include sheaths and dilators.

The Genie MAX and the GORE DrySeal Flex are the same device type and utilize the same fundamental technology, mode of action, and principles of operation. They are based on the same basic design, similar materials and device features are similar.

Technological differences between the Genie MAX and the predicate device are as follows:

- Specifications – the subject device offers different lengths of sheaths (15 – 65 cm) compared to the predicate device (33 – 65 cm).
- The subject and predicate device use different mechanisms to regulate the pressure within the hemostasis valve.
- The subject device uses different polymeric materials in the hub and sheath components than the predicate.

These differences do not raise any different questions of safety or effectiveness for the Genie MAX device compared to the predicate device.

## Performance Data

Based on the differences compared to the predicate device, the following types of testing have been completed for the Genie MAX device to support the substantial equivalence determination:

- Mechanical bench testing, including:
    - Dimensional verification
    - Simulated use
    - Tensile
    - Flexibility and kink
    - Torque strength
    - Radiopacity

  - Coating integrity
  - Surface inspection
  - Corrosion resistance
  - Freedom from leakage
  - Luer compatibility
  - Dilator removal force
  - Dilator to sheath securement
  - Particulate
- Biocompatibility testing
- Packaging validation
- Sterilization validation

The above comparison and performance testing together supported the substantial equivalence of the Genie MAX device to the predicate device.

# Conclusion

The Genie MAX device is substantially equivalent to the legally marketed predicate device.