July 6, 2026

Hartman Medical Group, LLC
Pooja Kannam
Director of Quality and Regulatory Affairs
2700 Corporate Dr.
Suite 200
Birmingham, Alabama 35242

Re: K261529
Trade/Device Name: Micropuncture Kit; Micropuncture Access Kit; Micropuncture Introducer Set; Microintroducer Kit; Microintroducer Set; Introducer Kit; Introducer Set; Micro Introducer Sheath Set; Introducer Sheath Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 7, 2026
Received: May 8, 2026

Dear Pooja Kannam:

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,

Brian D. Pullin -S

Brian Pullin
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)*
K261529

Device Name
Micropuncture Kit; Micropuncture Access Kit; Micropuncture Introducer Set; Microintroducer Kit; Microintroducer Set; Introducer Kit; Introducer Set; Micro Introducer Sheath Set; Introducer Sheath Set

Indications for Use *(Describe)*
The Introducer Set is intended to facilitate the introduction of guidewires, catheters, and other accessory medical devices through the skin into a vessel while maintaining hemostasis.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter Information

Hartman Medical Group, LLC
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Birmingham, AL 35242
Phone: 1-833-HMG-BHAM

Contact Person

Pooja Priyanka Kannam
Director of Quality & Regulatory Affairs
Hartman Medical Group, LLC

Date Prepared

May 2026

Device Trade Name

- Micropuncture Kit
- Micropuncture Access Kit
- Micropuncture Introducer Set
- Microintroducer Kit
- Microintroducer kit
- Microintroducer Set
- Introducer Kit
- Introducer Set
- Micro Introducer Sheath set
- Introducer Sheath set

Common / Usual Name

Introducer Set

Classification Name

Catheter, Introducer

Regulation Number

21 CFR 870.1340

Product Code

DYB

510(k) Summary

Predicate Device

Thinline Sheath Introducer
K232260

Reference Device

SUPER SHEATH
K141070

Device Description

The Introducer Set is a sterile, single-use device intended to facilitate percutaneous vascular access and introduction of guidewires, catheters, and other accessory medical devices into the vascular system while maintaining hemostasis.

The device family includes introducer sheath assemblies, dilators, guidewires, introducer needles, stopcocks, and accessory components in multiple configurations and sizes. The device is provided sterile using ethylene oxide sterilization.

The device incorporates polymeric and metallic materials including Fluorinated Ethylene Propylene (FEP), Polyvinyl Chloride (PVC), Polycarbonate (PC), High-Density Polyethylene (HDPE), Polypropylene (PP), Polyurethane (PU), Silicone Elastomer, Stainless Steel 304 (SUS304), and Nickel-Titanium alloy (Nitinol).

Indications for Use

The Introducer Set is intended to facilitate the introduction of guidewires, catheters, and other accessory medical devices through the skin into a vessel while maintaining hemostasis.

Comparison to Predicate Device

The subject device has the same intended use and similar technological characteristics as the predicate device identified above. Differences between the subject device and predicate device do not raise different questions of safety or effectiveness.

Performance testing demonstrated that the subject device performs comparably to the predicate device and supports substantial equivalence.

Performance Testing

Performance testing was conducted to support substantial equivalence of the subject device and included:

- Shelf-life testing
- Packaging validation
- Transportation validation
- EO sterilization validation
- Sterility testing

510(k) Summary

- Bacterial endotoxin testing
- Particulate matter evaluation
- Mechanical and dimensional testing
- Simulated use testing
- Biocompatibility testing

Biocompatibility

Biocompatibility evaluation was performed in accordance with ISO 10993-1 based on the nature and duration of patient contact. Testing included:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Acute systemic toxicity
- Material-mediated pyrogenicity
- Hemocompatibility evaluations

Sterilization

The device is terminally sterilized using Ethylene Oxide (EO) sterilization.

Sterilization validation was conducted in accordance with ISO 11135. The device was validated to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

EO residual testing was conducted in accordance with ISO 10993-7.

Conclusion

Based on the intended use, technological characteristics, and performance testing provided, the subject Introducer Set is substantially equivalent to the predicate device identified above.