



June 22, 2026

Health Line International Corporation
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K261950
Trade/Device Name: Health Line Tearaway Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 10, 2026
Received: June 10, 2026

Dear Prithul Bom:

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,

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Date: 2026.06.22
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Finn Donaldson
Acting 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

Indications for Use

510(k) Number (if known)
K261950

Device Name
Health Line Tearaway Introducer

Indications for Use (Describe)

The Health Line Tearaway Introducer is used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters, into the vasculature.

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
(21 CFR 807.92)

SUBMITTER	Name:	Health Line International Corporation
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	Email:	agfaulkner@hlic.net
	Date Prepared:	November 26, 2025

SUBJECT DEVICE	Name:	<i>Health Line Tearaway Introducer</i>
	Regulation Name:	Catheter Introducer
	Classification Name:	Introducer, Catheter
	Classification Panel:	Cardiovascular
	Regulatory Class:	Class II
	Product Code:	DYB
	Regulation Number:	21 CFR 870.1340

PREDICATE DEVICE	Name:	<i>Tearaway Introducer Sheath (K153533) by Galt Medical Corp.</i>
	Regulation Name:	Catheter Introducer
	Classification Name:	Introducer, Catheter
	Classification Panel:	Cardiovascular
	Regulatory Class:	Class II
	Product Code:	DYB
	Regulation Number:	21 CFR 870.1340

The *Health Line Tearaway Introducer* is a sterile, single-use vascular access device composed of two main components: an outer tearaway sheath and an inner dilator.

The outer tearaway sheath is manufactured as a one-piece molded hub with integral wings, attached to a cylindrical peelable cannula. The design allows the sheath to be split longitudinally along its entire length when minimal separating force is applied at the winged hub. This controlled tear mechanism enables safe and efficient removal of the sheath from around an indwelling catheter or other intravascular devices without exerting excessive force on the insertion site.

DEVICE DESCRIPTION

The inner dilator consists of a rigid cylindrical cannula integrally molded with a proximal female Luer hub to accommodate guidewire insertion. The distal end of the dilator is thermally tapered to facilitate atraumatic vessel entry. The dilator is designed to be longer than the tearaway sheath to provide optimal guidance during insertion. A snap-fit locking mechanism secures the dilator hub to the tearaway sheath hub, preventing relative movement during vascular access. This locking mechanism may be disengaged by applying a controlled rotational motion, permitting separation of the components when required.

The *Health Line Tearaway Introducer* is provided in different sizes which is indicated in the front face of the dilator hub.

INTENDED USE	The <i>Health Line Tearaway Introducer</i> is used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters, into the vasculature.
INDICATIONS FOR USE	The <i>Health Line Tearaway Introducer</i> is used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters, into the vasculature.

Subject Device: *Health Line Tearaway Introducer*
Predicate Device: *Tearaway Introducer Sheath (K153533)*

	ATTRIBUTES	SUBJECT DEVICE	PREDICATE DEVICE
TECHNOLOGICAL CHARACTERISTICS - COMPARISON	Intended use	The <i>Health Line Tearaway Introducer</i> is used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters, into the vasculature.	These introducers are used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads, into the vasculature.
	Indications for Use	The <i>Health Line Tearaway Introducer</i> is used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters, into the vasculature.	These introducers are used for the percutaneous introduction of diagnostic or therapeutic devices, such as catheters and pacing leads, into the vasculature.
	Intended duration	Transient (≤ 24 Hours)	Transient (≤ 24 Hours)
	Prescription device	Yes	Yes
	Insertion sites	Percutaneous	Percutaneous
	Insertion technique	Seldinger (Over the guidewire)	Seldinger (Over the guidewire)
	Intended population	Adults	Adults
	Size Configurations	3.5Fr - 6.5Fr	3Fr - 16Fr
	Length Configurations	5, 7, 10cm	5 - 30cm
	Design	The Health Line Tearaway Introducer Sheath assembly consists of an outer peelable sheath and a dilator. The tearaway sheath has a winged hub to initiate the tear in the sheath.	The Galt Tearaway Introducer Sheath assembly consists of an outer peelable sheath and a dilator. The tearaway sheath has a winged hub to initiate the tear in the sheath.
	Assembly	Tearaway Sheath/Dilator	Tearaway Sheath/Dilator
	Dilator lock	Yes	Yes
	Insertion markings	None	None
	Dilator tip design	Symmetrical soft tapered tip	Symmetrical soft tapered tip
	Shape design	Sheath hub: Winged Sheath cannula: Cylindrical Dilator hub: Round Dilator cannula: Cylindrical	Sheath hub: Winged Sheath cannula: Cylindrical Dilator hub: Round Dilator cannula: Cylindrical
	Color	Sheath: Color coded winged hub, gray cannula Dilator: White hub, white cannula	Sheath: Color coded winged hub, gray cannula Dilator: White hub, green cannula
	Winged hub material	Polypropylene	Polypropylene
	Sheath material	PTFE	PTFE
	Dilator hub material	Polyurethane	PEBAX
	Dilator cannula material	PEBAX	PEBAX

Size identification	Marked in dilator hub	Marked in dilator hub
Sterilization method	Ethylene Oxide	Ethylene Oxide
Method of use	Single use, disposable	Single use, disposable
Shelf life	3 years	4 years
Sterile barrier material	Tyvek	Tyvek
Conical fittings	ISO 80369-7 Compatible	ISO 80369-7 Compatible
Non-Pyrogenic	Yes	Yes
Made with latex rubber	No	No
Made with DEHP	No	No

The subject device has similar technological characteristics as compared to the predicate device. Differences, if any, are not critical to the intended use of the subject device (as discussed in the section corresponding to Substantial Equivalence Comparison) and do not raise new questions regarding safety and effectiveness.

The *Health Line Tearaway Introducer* followed verification and validation activities in accordance with Design Controls as per 21 CFR Section 820.30.

The following bench testing was conducted in the subject device to demonstrate substantial equivalence to the predicate device and verify conformity to international standards, FDA-recognized consensus standards and in-house requirements:

1. Hub Break Force
2. Sheath Peel Force
3. Dilator Break Force
4. Dilator Insertion Force
5. Guidewire Compatibility
6. Dimensional
7. Simulation Use

**SAFETY AND
PERFORMANCE
TESTING**

Functional testing was conducted in accordance with ISO 11135 and ISO 11607-1 to evaluate sterilization and shelf life of the finished subject device.

The following biocompatibility testing was conducted in accordance with ISO 10993-1 and based on a biological evaluation plan (BEP) and report (BER) to evaluate the subject device on:

1. Cytotoxicity
2. Sensitization
3. Irritation or Intracutaneous Reactivity
4. Acute Systemic Toxicity
5. Material Mediated Pyrogen
6. Hemocompatibility
7. Genotoxicity

Results of the biocompatibility testing support the determination of substantial equivalence.

**SUMMARY OF
SUBSTANTIAL
EQUIVALENCE**

Functional and biological comparison confirms that the technological characteristics between the subject and predicate devices are substantial equivalent, including:

- Principle of Operation
 - Design
 - Key Features
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- Material Composition
 - Sterilization
 - Biocompatibility
 - Performance Testing
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CONCLUSION

In accordance with FDA 21 CFR Section 807.92, and based on the indications for use, technological characteristics, biocompatibility and safety and performance testing, the subject Health Line Tearaway Introducer met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation, and indications for use to the currently marketed Tearaway Introducer Sheath (K153533) predicate device without raising any new questions regarding safety and effectiveness.
