Contract Medical International GmbH
Jan Kubicek
Senior Regulatory Affairs Manager, Europe
Lauensteiner Str. 37
Dresden, Saxony 01277
Germany

Re: K250439
Trade/Device Name: Catapult Guide Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB, DRE
Dated: February 14, 2025
Received: February 14, 2025

Dear Jan Kubicek:

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,

Sevan R. Oungoulian -S

Digitally signed by Sevan R. Oungoulian -S
Date: 2025.03.16 13:51:42 -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)*
K250439

Device Name
Catapult Guide Sheath Introducer Sheath System; COMPASS Guiding Introducer Sheath; Fortress Introducer Sheath System

Indications for Use *(Describe)*
The Catapult Guide Sheath is indicated to be used for introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature.

The COMPASS Guiding Introducer Sheath is indicated to be used for introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature. The device is also intended to be used within a pediatric population.

The Fortress Introducer Sheath System is intended to provide access and to facilitate percutaneous introduction of guide wires, catheters and other devices into the femoral, popliteal and infrapopliteal arteries while maintaining haemostasis during diagnostic and interventional procedures.

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

1.1 Submitter

Submitter:	Contract Medical GmbH Lauensteiner Strasse 37 01277 Dresden Germany
Contact Person:	Jan Kubicek,
Position:	Regulatory Affairs Manager
Phone:	+420494949556
Email:	jan.kubicek@heraeus.com
Date Summary Prepared:	14th February 2025

1.2 Device

Device Trade Name:	Catapult Guide Sheath
Device Common Name:	Introducer Sheath
Modification:	Introduction of internally sourced HVA
Classification Name:	Introducer Catheter, and Dilator, Vessel, For Percutaneous Catheterization
Device Class:	II
Product Code:	DYB, and DRE

1.3 Predicate Device

The predicate device is the Catapult Guide Sheath Introducer Sheath System (K240957).

1.4 Device Description

The Introducer Sheath System devices consist of a coil reinforced introducer sheath with hemostasis valve and side port, as well as a dilator with a tapered tip and luer lock at the proximal end. The main introducer sheath tubing is connected at the proximal end to a hemostasis valve with side port tubing that is connected to a plastic color coded 3-way stopcock valve. The side port is used for flushing the introducer sheath. The sheath is introduced into the vascular system with the aid of the dilator. The hemostasis valve at the proximal end of the introducer sheath conforms and seals around guide wires and catheters to reduce blood leakage from the introducer sheath. A radiopaque marker helps identify the distal end of the introducer sheath. The introducer sheath has a lubricious hydrophilic coating on the outer surface in length of 20cm on the distal portion.

The System consists of the following components:

- One Introducer Sheath with hemostasis valve
- One or two dilator(s)

1.5 Indications for Use for introducer sheath systems of the Manufacturer

The Catapult Guide Sheath is indicated to be used for introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature.

The COMPASS Guiding Introducer Sheath is indicated to be used for introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature. The device is also intended to be used within a pediatric population.

The Fortress Introducer Sheath System is intended to provide access and to facilitate percutaneous introduction of guide wires, catheters and other devices into the femoral, popliteal and infrapopliteal arteries while maintaining haemostasis during diagnostic and interventional procedures.

1.6 Comparison of Technological Characteristics with the Predicate Device

Regarding the design, device features, method of sterilization, and mode of operation, the modification of Introducer Sheath System device does not differ from the predicate device.

Device size configurations and shapes for the modified Introducer Sheath System devices are unchanged.

Materials used for manufacture of the modified Introducer Sheath System devices are the same or very similar as those contained in the predicate device with exception of the insourced HVA (Hemostasis Valve Adaptor).

The following modification exist between the subject and predicate devices:

- New insourced HVA as complete assembly

HVA Part	Predicate HVA materials	Subject HVA Materials
Hemostasis valve material	HVA Cap: Polycarbonate	HVA Cap: Copolyester
	HVA Body: Polycarbonate	HVA Body: Copolyester
	Valve membrane: Silicone	Valve membrane: Silicone
	Swivel Nut: Copolyester	Swivel Nut: Polycarbonate
	O-Ring: N/A	O-Ring: Silicone
	Lubricant: Silicone	Lubricant: Silicone
Stopcock and extension line material	Stopcock Body: Polycarbonate	Stopcock Body: Polycarbonate
	Stopcock Handle: Acetal	Stopcock Handle: HDPE
	Stopcock Cap: ABS	Stopcock Cap: Polypropylene
	Tubing: TPU - Tecothane	Tubing: TPU - Elastollan

Table 1 – HVA material comparison between subject and predicate device

1.7 Performance Data

Performance data demonstrate that the modification of the Introducer Sheath System devices is substantially equivalent to the predicate. The following performance data from non-clinical tests were provided in support of the substantial equivalence determination:

- Mechanical testing, including tests required under relevant international standards were performed to verify and validate the design.
- Biocompatibility Risk Assessment (BRA) and performed biocompatibility device testing to demonstrate biocompatibility.
- Sterilization information to confirm sterility of the device upon exposure to the selected sterilization EO cycle.
- Accelerated aging testing to confirm product performance at the end of the shelf life.

The list of tests performed in support of determination of substantial equivalence is provided in Table 2.

No.	Verification / Validation Activity	Test Type	Applicable Standard(s) (Recognized Consensus # if applicable]
1	**Dimensional Evaluation**	Visual	Internal requirement based on predicate performance
2	**Insertion Force**	Mechanical/Visual	Internal requirement based on predicate performance
3	**Valve / Dilator snap-in fit test**	Mechanical/Visual	Internal requirement based on predicate performance IEC 62366-1:2020 (5-129)
4	**Air leakage during aspiration**	Mechanical	ISO 10555-1:2013/AMD1:2017 (6-408)
5	**Liquid leakage through hemostasis valve**	Mechanical	ISO 11070:2014 ISO 10555-1:2013/AMD1:2017 (6-408) ISO 80369-1:2018 (5-121) ISO 80369-7:2021 (5-133)
6	**Tensile properties evaluation**	Mechanical	ISO 11070:2014 ISO 10555-1:2013/AMD1:2017 (6-408)
7	**Kink stability**	Mechanical	EN 13868:2002 (N/A) Internal requirement based on predicate performance
8	**Flow-rate**	Mechanical	ISO 10555-1:2013/AMD1:2017 (6-408)

No.	Verification / Validation Activity	Test Type	Applicable Standard(s) (Recognized Consensus # if applicable]
9	**Luer Connector**	Mechanical	ISO 80369-1:2018 (5-121) ISO 80369-7:2021 (5-133)
10	**Particle evaluation test**	Mechanical/Visual/External	AAMI TIR42 (3-172) ISO 8536-4 (6-447) USP <788>
11	**Packaging integrity assessment**	External laboratory testing	EN 868-5:2018 ASTM F88/F88M-21(14-573) ISO 11607-1 Second edition 2019-02 (14-530)
12	**Biocompatibility testing** **Biological Risk Assessment**	External Laboratory Documented assessment	ISO 10993-1:2018 (2-258) ISO 10993-4:2017 (2-248) ISO 10993-5:2009 (2-245) ISO 10993-10:2021 (2-296) ISO 10993-11:2017 (2-255) ISO 10993-12:2021 (2-289) ISO 14971:2019 (5-125) FDA Guidance Use of International Standard ISO 10993-1
13	**Chemical stability assessment**	Documented assessment	Internal requirement based on predicate performance
14	**Sterilization adoption**	Documented assessment / External laboratory testing	ISO 10993-7:2008 (2-275) ISO 11737-1:2018/AMD1:2021 (14-577) ISO 11135:2014 (14-529) ISO 10993-1:2018 (2-258) AAMI TIR28:2009 (N/A)
15	**Accelerated Age Study**	Mechanical/ External Laboratory	ASTM F1980-16 (14-497) Various per performed tests

Table 2 - Testing overview

1.8 Conclusions

The results of performed testing based on risk analysis demonstrate that the new modification of Introducer Sheath System devices perform comparably with the predicate and other legally marketed devices. The modified Introducer Sheath System devices with insourced HVA is substantially equivalent to the predicate device in terms of intended use, design and materials, technological characteristics, and principle of operation.