November 20, 2020

Contract Medical International, GmbH
Marketa Shanelova
Regulatory Manager
Lauensteiner Strasse 37
Dresden, Saxony 01277
Germany

Re: K203179
Trade/Device Name: Fortress Introducer Sheath System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DRE
Dated: October 23, 2020
Received: October 26, 2020

Dear Marketa Shanelova:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203179

Device Name
Fortress Introducer Sheath System

Indications for Use *(Describe)*

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 hemostasis 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.

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2 510(k) SUMMARY

2.1 Submitter

Submitter:	Contract Medical GmbH Lauensteiner Strasse 37 01277 Dresden Germany
Contact Person:	Marketa Shanelova, Regulatory Manager
Phone:	+420 494 949 586
Email:	marketa.shanelova@heraeus.com
Date Summary Prepared:	23 October 2020

2.2 Device

Device Trade Name:	Fortress Introducer Sheath System
Device Common Name:	Introducer Sheath
Classification Name:	Introducer Catheter, and Dilator, Vessel, For Percutaneous Catheterization
Device Class:	II
Product Code:	DYB, and DRE

2.3 Predicate Device

The predicate device is the 6F size of the Fortress Introducer Sheath System (K153197)

2.4 Device Description

The Fortress Introducer Sheath System consists of an 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 introducer 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 hydrophobic silicone coating on the outer surface of the distal 30cm portion.

The System consists of the following components:

- One Introducer Sheath (a) with hemostasis valve (b)
- One dilator (c)

(a) Shaft. The coil reinforced multi-layer polymer shaft contains a tapered tip at the distal end. A continuous inner PTFE tube forms the core of the shaft and provides a circular working lumen through which devices can be passed. A single, full length polyether (Pebax) tube creates the outer cover of the shaft. A stainless-steel flat wire coil is fused between the two polymer tubes along the entire

length of the shaft. Hydrophobic coating is applied along the distal 30cm of the outer layer for increased lubricity in this area. A radiopaque marker made of platinum iridium is embedded at the distal end of the shaft. At the proximal end of the shaft, a female, winged luer hub is over-molded onto the shaft to support handling and to provide for the connection for the hemostasis valve. The hub is color coded to match the French size of the device.

(b) Hemostasis valve. A removable hemostasis valve is thread onto the luer hub at the proximal end of the shaft. Inside the valve housing, a lubricated, silicone slit disc provides a seal around devices passed through the sheath, thereby preventing blood leakage through the valve. Just distal of the valve, the valve housing is connected to a side port tube leading to three-way stopcock valve. The side port is used for flushing the introducer sheath. At the proximal end of the valve housing, the color-coded housing cap provides a snap fit connection to the hub of the dilator.

(c) Dilator. The dilator made of Pebax contains a full length round lumen to allow placement over a guide wire. The distal end of the dilator is configured as a tapered tip that extends 35+/-7mm beyond the end of the sheath when the dilator is fully inserted through the sheath. An integral, color coded luer hub that is over-molded onto the proximal end of the dilator supports handling of the dilator and provides a snap fit connection to the valve housing cap at the proximal end of the sheath introducer.

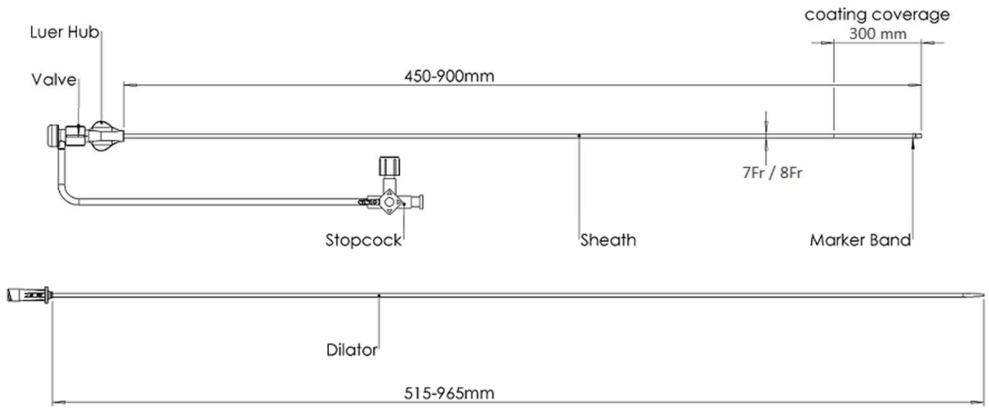
The shaft and hemostasis valve are pre-assembled and packaged together with a dilator. Each shaft and each dilator are placed in a separate protection tube, the protection tubes are clamped together with clips. Products are sealed inside an inner and outer medical grade Tyvek pouch on which a product label is placed. Devices are packaged in labeled packers containing five units and one Instruction for Use (IFU) booklet.

The Fortress Introducer Sheath System is a sterile, disposable device. It is a prescription medical device that is used only in healthcare facilities or hospitals. The device is placed in patients for up to 24 hours.

Devices are sterilized using ethylene oxide (maximum levels of remaining tested sterilant residuals of EO < 2.9mg/24h and ECH < 1mg/24h; sterilant residual limits of EO < 4mg/24h and ECH < 9mg/24h; Sterility Assurance Level, SAL 10^{-6}).

2.5 Physical Description

The schematic diagram below illustrates the range of dimensions for the new 7/8F models.



2.6 Device Models

French Size	Length (cm)	Shape	Catalogue Number
7F	45	Crossover	452386
7F	45	Straight	452382
7F	65	Straight	452383
7F	90	Straight	452388
8F	45	Crossover	452387
8F	45	Straight	452385
8F	65	Straight	452384
8F	90	Straight	452389

2.7 Materials Used

The materials that make up the device are either the same or very similar to those used for the predicate. Any differences in the material do not raise any new issues of safety or effectiveness, as demonstrated by the design verification test results.

2.8 Indications for Use

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 hemostasis during diagnostic and interventional procedures.

This is the same intended use as for the previously cleared 6F Fortress Introducer Sheath System (K153197).

2.9 Comparison of Technological Characteristics with the Predicate Device

The 7F and the 8F size of the Fortress Introducer Sheath System is a manually operated, sterile, single patient use sheath system made predominantly of thermoplastic polymers. The sheath is reinforced with a stainless steel coil in order to provide kink resistance when passed through tortuous paths. With regard to the design, device features, method of sterilization, and mode of operation, the 7F and 8F Fortress Introducer Sheath System does not differ from the predicate device.

Materials used for manufacture of the 7F and 8F Fortress Introducer Sheath System are the same or very similar as those contained in the predicate device. The slight differences in technological characteristics between the subject device and the predicate do not raise any new concerns of safety and effectiveness, as demonstrated by the data collected.

2.10 Performance Data

Performance data demonstrate that the Fortress Introducer Sheath System 7F and 8F performance is substantially equivalent to the predicate. The following performance data from non-clinical tests are being provided in support of the substantial equivalence determination:

- Mechanical testing, including tests required under relevant international standards, and usability test 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 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 the table below.

List of Tests

No.	Verification / Validation Activity	Test Type	Applicable Standard(s)
1	**Sheath/dilator fit test**	Mechanical/Visual	Internal requirement
2	**Sheath pull out test**	Mechanical/Visual	ASTM F2394 ISO 10555-1:2013
3	**Sheath kink resistance test**	Mechanical	EN 13868:2002
4	**Sheath force at break test**	Mechanical	ISO 10555-1:2013
5	**Sheath creep to break test**	Mechanical	ISO 10555-1:2013
6	**Dilator hub bond strength**	Mechanical	ISO 10555-1:2013
7	**Sheath system insertion force**	Mechanical	Internal requirement
8	**Usability evaluation**	Usability Study	IEC 62366-1:2015
9	**Simulated use test**	Mechanical/Visual	ASTM F2394
10	**Accelerated age test** (3 years)	Mechanical/ External Laboratory	ASTM F1980-16 Various per performed tests
11	**Biocompatibility testing** Cytotoxicity test **Biological Risk Assessment**	External Laboratory Documented assessment	ISO 10993-1:2009 ISO 10993-4:2017 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2017 ISO 10993-12:2012

No.	Verification / Validation Activity	Test Type	Applicable Standard(s)
			ISO 14971:2019 FDA Guidance Use of International Standard ISO 10993-1
12	**Sterilization adoption**	Documented assessment/ External laboratory testing	ISO 10993-7:2008 ISO 11737-1:2018 ISO 11135:2014 ISO 10993-1:2018

2.11 Conclusions

The results of performed testing based on risk analysis demonstrate that the 7F and 8F Fortress Introducer Sheath System performs comparably with the predicate. The 7F and 8F Fortress Introducer Sheath System is substantially equivalent to the predicate device in terms of intended use, design and materials, technological characteristics, and principle of operation. Any differences between the subject device and the predicate do not raise any new issues of safety or effectiveness.