



Food and Drug Administration
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Silver Spring, MD 20993-0002

January 11, 2016

Contract Medical International, GmbH
c/o Ms. Jan Kloboucnik
Director, RA/QA
Lauensteiner Straße 37
01277 Dresden, Germany

Re: K153197

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: December 11, 2015
Received: December 14, 2015

Dear Ms. Kloboucnik:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153197

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.

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510(k) SUMMARY

1.1 Submitter

Submitter:	Contract Medical GmbH Lauensteiner Strasse 37 01277 Dresden Germany
Contact Person:	Jan Kloboucnik, Director RAQA
Phone:	+420 494 949 564
Email:	jkloboucnik@contract-medical.com
Date Summary Prepared:	11 th January 2016

1.2 Device

Device Trade Name:	Fortress Introducer Sheath System
Device Common Name:	Introducer Sheath
Classification Name:	Introducer Catheter 21CFR Part 870.1340, and Dilator, Vessel, For Percutaneous Catheterization 21CFR Part 870.1310
Device Class:	II
Product Code:	DYB, and DRE

1.3 Predicate Device

The predicate device is the 4F size of the Fortress Introducer Sheath System (K100799)

1.4 Device Description

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.

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 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 (5F and 6F sizes) has a hydrophobic silicone coating on the outer surface of the distal 30cm portion.

The System consists of the following components:

- One Introducer Sheath with hemostasis valve
- Two dilators: 5F and 6F 100cm version
- One dilator: 5F and 6F 45cm version

1.5 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 4F Fortress Introducer Sheath System, model numbers 358813, 358814 and 358815 (K100799).

1.6 Comparison of Technological Characteristics with the Predicate Device

The 5F and the 6F 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 5F and 6F Fortress Introducer Sheath System does not differ from the predicate device.

Materials used for manufacture of the 5F and 6F Fortress Introducer Sheath System are the same or very similar as those contained in the predicate device. Technological characteristics of the subject device differ from those of the predicates only with respect to addition of lubricious coating on the sheath. The hydrophobic coating applied to the distal end of the sheath is commonly used in medical devices, including introducer sheaths and catheters. Differences in technological characteristics between the subject device and the predicate do not raise and concerns of safety and effectiveness, as demonstrated by the data collected.

1.7 Substantial Equivalence

Verification and validation tests were designed and performed in accordance with Design Controls as per 21 CFR §820.30. The following tests were conducted per guidance documents and standards to determine appropriate methods for evaluating the performance of the device and determine substantial equivalence:

Test Name	Test Method	Test Result
Balloon Pull Back Test (Robustness Test)	Visual Inspection Dimensional Inspection Insertion Force Test Pull Back Force Test Destructive Pull Test	Passed
Accelerated Aging	Visual Inspection Coating Integrity Sheath Liquid Leakage - (Pressure Test) Sheath System Insertion Force Sheath Pull Out Test Sheath Kink Resistance Sheath Creep To Break Sheath Force At Break Dilator Force At Break	Passed

Test Name	Test Method	Test Result
Valve Leak Test	Pressure Test	Passed
Particulates Evaluation Test	Membrane Filtration	Passed
Biological Risk Assessment Cytotoxicity	Qualitative Evaluation Quantitative Evaluation	Passed
Pig Skin Test	Insertion Force Test	Passed
Visibility under X-ray	X-Ray Test	Passed
Packaging Integrity Validation	Visual Inspection Dye Penetration Test Peel Test Balloon Pull Back Test Kink Test Creep Test Pull Test	Passed
Sterilization Validation	LAL – Pyrogenicity Testing Bioburden Bioburden Recovery Factor Determination EO/ECH Residuals	Passed
LAL Validation	Gel Clot Method	Passed

Acceptance criteria were met for all performed tests, the results showed that the modifications do not have negative impact on the device safety and effectiveness of the device.

1.8 Conclusions

The results of performed testing based on risk analysis demonstrate that the 5F and 6F Fortress Introducer Sheath System performs comparably with the predicate and other legally marketed devices.

The 5F and 6F 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 issues of safety or effectiveness.