K100799

SECTION 1. 510(K) SUMMARY

FEB 25 2011

Submission Owner / Correspondent:	Jan Kloboucnik Director, RA/QA Contract Medical, GmbH Zur Wetterwarte 50 01109 Dresden, Germany Phone: +420 494949564 Fax: +420 494949565 Email: jklobouchik@contract-medical.com Contact: Jan Kloboucnik
Device Manufacturer	Contract Medical Intl. GmbH Zur Wetterwarte 50 House 302 Dresden, GERMANY 01109 **Registration Number:** 3003637635
Date summary prepared:	December 22, 2010 (supersedes original summary from March 18, 2010)
Device trade name:	Fortress Introducer Sheath System
Device common name:	Introducer Sheath
Device classification name:	Catheter Introducer DYB, Class II per 21 CFR 870.1340, and Dilator, Vessel, For Percutaneous Catheterization DRE, class II at 21 CFR Part 870.1310

Legally marketed device to which the device is substantially equivalent:

Manufacturer	Device Name	510(k) Number
Merit Medical Systems, Inc.	Prelude and Prelude Pro Sheath Introducers	K073035
Terumo Medical Corporation	Pinnacle Destination Peripheral Guiding Sheaths	K091329

Description of the device:

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 Fortress Introducer Sheath System consists of the following components:

- One: introducer sheath
- Two: dilators

Intended use of the device:	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 while maintaining hemostasis during diagnostic and interventional procedures. The device is designed to facilitate easier access to the femoral, popliteal and infrapopliteal arteries by means of the crossover approach, which would otherwise be difficult or impossible to access by conventional means, as exemplified in patients with damaged, occluded or blocked vessels. The Fortress Introducer Sheath System is intended to be used by physicians trained in performing arterial catheterizations, primarily in hospital environment.
Technological characteristics:	The proposed device has the same technological characteristics as the predicate devices.
Conclusions:	The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Contract Medical GmbH
c/o Ms. Jan Kloboucnik
Director, RA/QA
Zur Wetterwarte 50
01109 Dresden, Germany

FEB 25 2011

Re: K100799
Trade/Device Name: Fortress Introducer Sheath System Model 358813, 358814 and 358815
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: December 22, 2010
Received: December 29, 2010

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K100799

Device Name: Fortress Introducer Sheath System

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 while maintaining hemostasis during diagnostic and interventional procedures.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100799