July 29, 2022

Contract Medical International s.r.o.
Jan Kubicek
Senior Regulatory Specialist
Vazni 848
Hradec Kralove, 50011
Czech Republic

Re: K221914
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: June 27, 2022
Received: June 30, 2022

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 (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,

Finn Donaldson
Team Lead
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)*
K221914

Device Name
Catapult Guide Sheath

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.

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:	Juliana Vaz Nuernberger,
Position:	Global Head of Regulatory Affairs
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Date Summary Prepared:	28th July 2022

1.2 Device

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

1.3 Predicate Device

Predicate device: DuraSheath Introducer Sheath System (K181463)

Reference device: R2P Destination Slender Guiding Sheath (K193125)

1.4 Device Description

The Catapult Guide Sheath consists 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 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 lubricious hydrophilic coating on the outer surface up to 20cm on the distal portion.

The System consists of the following components:

- One Introducer Sheath) with hemostasis valve
- One dilator or
- Two dilators for 15 cm version

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 fixated onto a packaging pad. Products are sealed inside a 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 Catapult Guide Sheath is a sterile, disposable device. It is a prescription medical device that is used only in healthcare facilities or hospitals. The device is suitable for placement in patients for up to 24 hours.

Devices are sterilized using ethylene oxide. Maximum levels of remaining tested sterilant residuals meet requirement limits EO < 4mg/24h and ECH < 9mg/24h; while achieving Sterility Assurance Level SAL 10^{-6}.

1.5 Physical Description

The Catapult Guide Sheath exists in 4 French, 5 French, 6 French, 7 French and 8 French sizes, each with effective lengths of 15 cm, 45 cm, 60 cm, or 90 cm.

Selected product versions are manufactured in one or more of the following shapes - Left Internal Mammary Artery (LIMA), Hockey Stick (HS), Multi-Purpose (MP) and Renal Double Curve (RDC). The shape of sheaths is formed by heating of distal part of straight product versions.

1.6 Device Models

ID (French)	Length	Coating		Straight	Multipurpose (MP)	Left Internal Mammary Artery (LIMA)	Renal Double Curve (RDC)	Hockey Stick (HS)
4F	15cm	5cm		x				
4F	45cm	10cm		x				
4F	60cm	10cm		x				
4F	90cm	20cm		x				
5F	15cm	5cm		x				
5F	45cm	10cm		x	x		x	x
5F	60cm	10cm		x				
5F	90cm	20cm		x				
6F	15cm	5cm		x				
6F	45cm	10cm		x	x	x	x	x
6F	60cm	10cm		x				
6F	90cm	20cm		x	x		x	x
7F	15cm	5cm		x				
7F	45cm	10cm		x	x	x	x	x
7F	60cm	10cm		x				

7F	90cm	20cm		x	x			x
8F	15cm	5cm		x				
8F	45cm	10cm		x				
8F	60cm	10cm		x				
8F	90cm	20cm		x				

Table 1 - Catapult Guide Sheath Device Models

1.7 Indications for Use

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

1.8 Device Comparison

The new versions of the Catapult Guide Sheath are 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. Regarding the design, device features, method of sterilization, and mode of operation, the new versions of Catapult Guide Sheath does not differ from the predicate device.

Materials used for manufacture of the new Catapult Guide Sheath are the same or very similar as those contained in the predicate device.

Characteristics	**Subject Device** **Catapult Guide Sheath**	**Predicate** **DuraSheath Introducer Sheath System**
Trade name	Catapult Guide Sheath	DuraSheath Introducer Sheath System
Indications for use	The Catapult Guide Sheath is indicated to be used for introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature. * These Indications for Use for the subject device are a subset of those cleared for the Predicate	The DuraSheath Introducer Sheath System 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.
Principle of operation	Manual operation where the sheath is inserted and removed over dilator and guidewire	Same
French sizes	4F to 8F	Same
Effective lengths	15, 45, 60 and 90cm	Same
Shaft distal shape configuration	Straight and curved	Straight
Hemostasis valve	Polycarbonate (Valve body and cap)	Same

Characteristics	Subject Device Catapult Guide Sheath	Predicate DuraSheath Introducer Sheath System
material	Silicone (Valve disc +lubricant)	
Hemostasis valve design	Removable hemostasis valve (disk valve) with side port	Same
Side port for flushing	Side port tubing with a color coded 3-way stopcock	Same
Stopcock material	Polycarbonate (body) Acetal (handle) Polyurethane (extension line)	Same
Shaft outer layer (cover) material	Pebax Colorant	Polyurethane (some models) Pebax Colorant
Shaft reinforcement material	Stainless steel coil	Same
Shaft inner layer (liner) material	PTFE inner layer	Same
Shaft proximal connection	Luer connector	Same
Shaft / Dilator luer hub	Luer hub (Pebax), colour coded	Same
Lubricious coating	Hydrophilic coating	Hydrophobic coating
Shaft radiopaque marker	Platinum iridium marker at the distal end	Same
Dilator material	Pebax with Barium sulphate (Dilator body) Pebax (Dilator hub)	Same
Dilator design	Tapered tip on dilator. Color coded hub. Snap fit between dilator and valve cap. Shape - Straight	Same
Guidewire included	No	Same
Radiation safety	Fluoroscopy allowed.	Same
Sterile package	Pouch	Same
Sterilization method / Sterilization Assurance Level (SAL)	Ethylene oxide cycle SAL 10^{-6}	Same
Shelf Life	3 years	Same
Compatibility with other devices	Guidewires up to 0.018 (15cm version only), 0,035 for 4F-6F and 0.038 7F-8F inches and instruments up to inner diameter for introducer sheath.	Same
French Size/Guidewire compatibility marking	French size of the devices is differentiated by color-coding of sheath and dilator Luer hub. Maximum guide wire size is referenced in labelling or in case of 15cm version additionally on dilator hub.	Same

Table 2 - Device Comparison

1.9 Performance Data

Performance data demonstrate that the new Catapult Guide Sheath is substantially equivalent to the predicate. The following performance data from non-clinical tests support 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 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 3.

No.	Verification / Validation Activity	Test Type	Results	Applicable Standard(s) (Recognized Consensus # if applicable]
1	**Visual and Dimensional Evaluation**	Visual	Pass	Internal requirement
2	**Sheath/dilator fit test**	Mechanical/Visual	Pass	Internal requirement
3	**Sheath pull out test**	Mechanical/Visual	Pass	ISO 10555-1:2013 (6-408) IEC 62366-1:2020 (5-129) Internal requirement
4	**Coating integrity**	Mechanical/Visual	Pass	Internal requirement Compared to reference device: R2P Destination Slender Guiding Sheath (K193125)
5	**Sheath Liquid Leakage** **Liquid leakage through hemostasis valve**	Mechanical/Visual	Pass	ISO 11070:2014 (N/A) ISO 10555-1:2013 (6-408)
6	**Coating integrity – Particle evaluation test**	Mechanical/Visual	Pass	AAMI TIR42 (3-172) ISO 8536-4 (6-447) USP <788> (N/A for medical devices) Compared to reference device: R2P Destination Slender Guiding Sheath (K193125)

No.	Verification / Validation Activity	Test Type	Results	Applicable Standard(s) (Recognized Consensus # if applicable]
7	**Sheath kink resistance test**	Mechanical	Pass	EN 13868:2002 (N/A) Internal requirement
8	**Sheath force at break test** **Sheath creep to break test** **Dilator hub bond strength**	Mechanical	Pass	ISO 10555-1:2013 (6-408) ISO 11070:2014 (N/A) Internal requirement
9	**Sheath Stiffness test**	Mechanical	Pass	Internal requirement
10	**Usability evaluation** **Simulated use test**	Usability Study	Pass	IEC 62366-1:2020 (5-129) Internal requirement
11	**Accelerated Age Study**	Mechanical/ External Laboratory	Pass	ASTM F1980-16 (14-497) Various per performed tests
12	**Biocompatibility testing** Cytotoxicity Hemolysis Partial Thromboplastin Time (PTT) Complement activation **Biological Risk Assessment**	External Laboratory Documented assessment	Pass	ISO 10993-1:2018 (2-258) ISO 10993-4:2017 (2-248) ISO 10993-5:2009 (2-245) ISO 10993-10:2010 (2-174) ISO 10993-11:2017 (2-255) ISO 10993-12:2012 (2-191) ISO 14971:2019 (5-125) FDA Guidance Use of International Standard ISO 10993-1
13	**Sterilization adoption**	Documented assessment / External laboratory testing	Pass	ISO 10993-7:2008 (14-408) ISO 11737-1:2018 (14-514) ISO 11135:2014 (14-529) ISO 10993-1:2018 (2-258) AAMI TIR28:2009 (N/A)
14	**Visibility of the sheath under X-ray**	Documented assessment	Leveraged from predicate	ASTM F 640-20 (8-556) ISO 11070:2014 (N/A)
15	**Packaging integrity assessment**	Documented assessment	Leveraged from predicate	EN 868-5:2019 ASTM F88/F88M-15(14-482) ISO 11607-1 Second edition 2019-02 (14-530)

Table 3 - Testing overview

1.10 Conclusions

Based on the intended use, technological characteristics, and performance data provided, the Catapult Guide Sheath is considered appropriate for the intended use. The technological and material differences between the subject and predicate devices do not raise new questions of safety or effectiveness. The subject Catapult Guide Sheath device is considered to be substantially equivalent to the predicate DuraSheath Introducer Sheath System (K181463).