August 14, 2024

Contract Medical International GmbH
Jan Kubicek
Regulatory Affairs Manager
Lauensteiner Strasse 37
Dresden, Saxony 01277
Germany

Re: K240957
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: April 8, 2024
Received: July 17, 2024

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.

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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2024.08.14 10:25:20 -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)*
K240957

Device Name
Catapult Guide Sheath

Indications for Use *(Describe)*
The Catapult TM 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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
Phone:	+49 351 210 747-19
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Date Summary Prepared:	8th April 2024

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, DRE

1.3 Predicate Device

The predicate device is the Catapult ™ Guide Sheath Introducer Sheath System (K221914).

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 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 of its distal 20cm.

The Catapult ™ Guide Sheath was previously cleared under K221914 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. This 510(k) adds a 130 cm length which is available in 4 French, 5 French and 6 French sizes.

1.5 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.

1.6 Comparison of Technological Characteristics with the Predicate Device

The differences in technological characteristics between the subject device and the predicate are the following:

- The maximum usable length was extended with the new version to 130 cm.
- Shaft Luer hub and Dilator resin material changed from PEBAX to RILSAMID.

1.7 Performance Data

Performance data were used to demonstrate that the new 130cm version of Catapult ™ Guide Sheath is substantially equivalent to the predicate:

- 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 support adoption of the device into the existing 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 Table 1.

Table 1 – Performance Testing Oerview

No.	Verification / Validation Activity	Test Type	Applicable Standard(s)
1	**Visual and Dimensional Evaluation**	Visual	Internal requirement
2	**Sheath/dilator fit test**	Mechanical/Visual	Internal requirement
3	**Sheath pull out test**	Mechanical/Visual	ISO 10555-1:2013/AMD1:2017 IEC 62366-1:2020 Internal requirement
4	**Coating integrity**	Mechanical/Visual	Internal requirement
5	**Sheath Liquid Leakage** **Liquid leakage through hemostasis valve**	Mechanical/Visual	ISO 11070:2014 ISO 10555-1:2013/AMD1:2017 ISO 80369-1:2018 ISO 80369-7:2021
6	**Coating integrity – Particle evaluation test**	Mechanical/Visual	AAMI TIR42 ISO 8536-4 USP <788>

7	**Sheath kink resistance test**	Mechanical	EN 13868:2002 Internal requirement
8	**Sheath force at break test** **Sheath creep to break test** **Dilator hub bond strength**	Mechanical	ISO 10555-1:2013/AMD1:2017 ISO 11070:2014 Internal requirement
9	**Sheath Stiffness test**	Mechanical	Internal requirement
10	**Usability evaluation** **Simulated use test**	Usability Study	IEC 62366-1:2020Internal requirement
11	**Accelerated Age Study**	Mechanical/ External Laboratory	ASTM F1980-16 Various per performed tests
12	**Biocompatibility testing** Cytotoxicity test **Biological Risk Assessment**	External Laboratory Documented assessment	ISO 10993-1:2018 ISO 10993-4:2017 ISO 10993-5:2009 ISO 14971:2019
13	**Sterilization adoption**	Documented assessment / External laboratory testing	ISO 10993-7:2008 ISO 11737-1:2018/AMD1:2021 ISO 11135:2014 ISO 10993-1:2018 AAMI TIR28:2009
14	**Visibility of the sheath under X-ray**	Documented assessment	ASTM F640-20 ISO 11070:2014
15	**Packaging integrity assessment**	External laboratory testing	EN 868-5:2018 ASTM F88/F88M-21 ISO 11607-1 Second edition 2019-02

1.8 Conclusions

The results of performed testing demonstrated that the new 130cm version of Catapult ™ Guide Sheath has substantially equivalent performance to the predicate. The new Catapult ™ Guide Sheath is substantially equivalent to the predicate device in terms of intended use, design and materials, technological characteristics, and principle of operation.