December 13, 2018

Contract Medical International GmbH
Jan Kloboucnik
Director, Regulatory and Quality Affairs
Lauensteiner Str. 37
Dresden, 01277 De

Re: K181463
Trade/Device Name: DuraSheath Introducer Sheath System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB, DRE
Dated: November 7, 2018
Received: November 9, 2018

Dear Jan 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Goodsell -S

Digitally signed by Nicole M. Goodsell -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001567081, cn=Nicole M. Goodsell -S
Date: 2018.12.13 09:10:57 -05'00'

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181463

Device Name
DuraSheath Introducer Sheath System

Indications for Use *(Describe)*
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.

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 (K181463)

I. SUBMITTER

Submitter:	Contract Medical International GmbH Lauensteiner Straße 37 01277 Dresden Germany
Contact Person:	Jan Kloboucnik, Director RA/QA
Phone:	+420 494 949 564
Fax:	+49 351 213 88 99
Email:	jkloboucnik@contract-medical.com
Date Prepared:	13 Dec 2018

II. DEVICE

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

III. PREDICATE DEVICE

Primary Predicate Device:	DuraSheath Introducer Sheath System (K142357)
Secondary Predicate Device:	Pinnacle Destination Guiding Sheath (K091329)

IV. DEVICE DESCRIPTION

The DuraSheath Introducer Sheath System is a sterile, disposable device consisting of (a) a coil reinforced shaft with an atraumatic tip at the distal end; (b) a hemostasis valve with a side port and color coded 3-way stopcock; and (c) a tapered tip dilator with snap-fit hub at the proximal end.

(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

polyurethane 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 part of the outer layer for increased lubricity in this area. The coating coverage depends on the model. 15 cm product versions have 10 cm portion of the shaft coated, while 45 cm, 60 cm and 90 cm product versions have 15 cm portion of the shaft coated. 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 TPE 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 about 2 cm 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 the hemostasis valve are pre-assembled and packaged together with one or two dilators (depending on the model), that is 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 device has a shelf life of three years.

The DuraSheath Introducer Sheath System 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}).

Operation and Compatibility

The device is operated manually and is to be handled aseptically by qualified medical personnel familiar with its application. The device includes metal components and cannot be exposed to MRI.

After removal from the sterile pouch packaging using aseptic techniques, the device is placed into the vasculature. Prior to use, the introducer sheath and dilator are flushed with heparinized solution. The dilator is then inserted completely into the introducer sheath and locked into place through the snap fit connection at the housing of the hemostasis valve. The dilator-sheath-combination is then passed as one unit over a guide wire with a maximum size of up to 0.035 inches for 4 French, 5 French and 6 French models, up to 0.038 inches for 7 French and 8 French models. 15 cm models contain an additional dilator compatible with guidewires up to 0.018 inches. Guide wire is not part of the device. Once the introducer sheath is fully placed in the patient, the guide wire and dilator are removed and compatible catheters and instruments can be inserted through the introducer sheath.

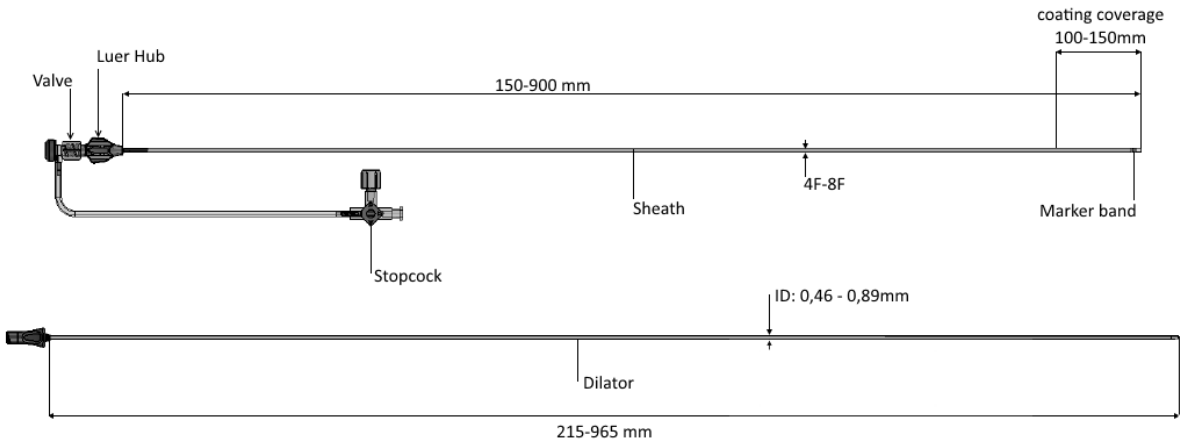
The various models of the device are compatible with catheters and instruments with outside diameters up to the French size labeled for each model. The DuraSheath Introducer Sheath System is placed in patients for several hours depending on the procedure type for which the compatible catheters and other instruments are intended, but the maximum time is up to 24 hours (i.e. biocompatibility contact classification of less than 24-hour duration).

For removal of the sheath, a guide wire is inserted past the distal tip of the sheath and the dilator is passed over the wire into the sheath. Sheath and dilator are then removed as one unit.

No energy source nor software are employed in the operation of the device. The device includes no electrical components and therefore does not require EMC and Electrical safety evaluation.

Physical Description

The schematic diagram below illustrates the range of dimensions for the full range of models.



Device Models

The DuraSheath Introducer Sheath System contains twenty (20) models with different sizes (4 French, 5 French, 6 French, 7 French and 8 French) and effective lengths (15 cm, 45 cm, 60 cm and 90 cm). Different model numbers and configurations are listed in the table below.

Device Model Numbers

Length/ Size	15 cm	45 cm	60 cm	90 cm
4 French	FG-04015	FG-04045	FG-04060	FG-04090
5 French	FG-05015	FG-05045	FG-05060	FG-05090
6 French	FG-06015	FG-06045	FG-06060	FG-06090
7 French	FG-07015	FG-07045	FG-07060	FG-07090
8 French	FG-08015	FG-08045	FG-08060	FG-08090

All models have the same design and contain identical features. Manufacturing processes are identical across sizes and lengths.

Materials Used

Materials used for the manufacture of the DuraSheath Introducer Sheath System are listed in the table below. The materials that make up the device are either the same or very similar to those used for the predicates. Any differences in material do not raise any issues of safety or effectiveness, as demonstrated by the design verification test results.

Materials Contained in the Device

Part Description	Material	Patient Contact
Shaft outer cover	Polyurethane, colour additives, hydrophobic coating	Direct
Shaft inner liner	PTFE	Indirect
Coil between inner and outer shaft layers	Stainless steel	None
Shaft luer hub	TPE - thermoplastic elastomer, colour additives	Direct
Shaft marker band	Platinum iridium	None
Valve body and cap	Polycarbonate, colour additives	Indirect
Valve disc	Silicone	Indirect
Valve disc lubricant fluid	Silicone	Indirect

Part Description	Material	Patient Contact
Swivel nut	Copolyester	None
Stopcock extension line	TPU-thermoplastic polyurethane	Indirect
Stopcock valve cap	ABS, colour additives	Indirect
Stopcock	Polycarbonate - body, Acetal – handle, colour additives	Indirect
Dilator body	TPE - thermoplastic elastomer with 20% Barium-sulphate (4F) or with 30% Barium-sulphate (5F, 6F, 7F, 8F)	Direct
Dilator Luer hub	TPE - thermoplastic elastomer, colour additives	Indirect

V. INDICATIONS FOR USE

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.

The Indications for Use statement for the DuraSheath Introducer Sheath System is not identical to that of the two legally marketed predicate devices; however, the differences are not critical as they do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate devices when used as labeled. The DuraSheath Introducer Sheath System and the two predicate devices each have the same intended use, namely to support the introduction of interventional and diagnostic devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The DuraSheath 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 DuraSheath Introducer Sheath System does not differ from the predicate devices. Materials used for manufacture of the DuraSheath Introducer Sheath System are identical as for the legally marketed primary predicate device, or very similar to those contained in the legally marketed secondary predicate devices.

Technological characteristics of the subject device do not differ from the primary predicate devices and differ from the secondary predicate only with respect to materials for selected components and the choice of lubricious coating on the sheath. Both the polyurethane used for the outer layer and the hydrophobic coating applied to the distal end of the sheath of the

DuraSheath Introducer Sheath System are commonly used in medical devices, including introducer sheaths and catheters and are identical with those used in the primary predicate. There are no differences in the material and technological characteristics between the subject device and the primary predicate device.

Differences in technological characteristics between the subject device and the secondary predicate do not raise and concerns of safety and effectiveness, as demonstrated by the performance data collected.

VII. PERFORMANCE DATA

Nonclinical and clinical performance data demonstrate that the DuraSheath Introducer Sheath System is safe and effective and its performance is substantially equivalent to the predicates. 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, coating adhesion and particulate testing, and transportation integrity testing, 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 end of 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	Internal requirement
2	**Sheath pull out test**	Mechanical	ASTM F2394 ASTM 1929-15 EN 868-5 ISO 11737-2 Internal requirement
3	**Sheath kink resistance test**	Mechanical	EN 13868:2002
4	**Sheath force at break test**	Mechanical	ISO 11070:2014 ISO 10555-1:2013
5	**Sheath creep to break test**	Mechanical	ISO 11070:2014 ISO 10555-1:2013

No.	Verification / Validation Activity	Test Type	Applicable Standard(s)
6	**Sheath system insertion force**	Mechanical	Internal requirement
7	**Coating integrity test**	Mechanical (External Laboratory)	Internal requirement
8	**Coating integrity test (particle evaluation)**	Mechanical (External Laboratory)	AAMI TIR42:2010 ASTM F2394 ISO 8536-4:2010 Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters USP 788
9	**Sheath Liquid Leakage**	Mechanical	ISO 11070:2014 ISO 10555-1:2013
10	**Valve Leak Test**	Mechanical	ISO 11070:2014
11	**Dilator hub bond strength**	Mechanical	ISO 11070:2014 ISO 10555-1:2013
12	**Sheath stiffness test**	Mechanical	Internal requirement based on ISO 178:2010
13	**EO Sterilization Validation**	External service provider	ISO 11135-1:2007 ISO 10993-7:2008 ISO 11737-1:2006 AAMI TIR28:2009 ANSI/AAMI ST72:2011
14	**Sterilization adoption**	Documented assessment/ External laboratory testing	AAMI TIR28:2009
15	**Accelerated age test** (3 years)	Mechanical/ External Laboratory	ASTM F1980-16 Various per performed tests
16	**Package integrity testing**	Mechanical/External laboratory	ISO 11607-1:2006 ISTA 2A:2011 ASTM F 1929-12 ASTM F1886:1998 EN 556-1 EN 13868:2002 EN 868-5 Annex D ISO 11070:1998
17	**Simulated use test**	Mechanical	Internal requirement

No.	Verification / Validation Activity	Test Type	Applicable Standard(s)
18	**Biocompatibility testing** Cytotoxicity test Thromboresistance Complement activation Hemolysis Pyrogenity Acute Systemic Toxicity Irritation Sensitization	External Laboratory	ISO 10993-1:2009 ISO 10993-4:2017 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2017 ISO 10993-12:2012
19	**Biological Risk Assessment**	Documented assessment	ISO 10993-1:2009 EN ISO 14971:2012 FDA Guidance Use of International Standard ISO 10993-1
20	**Testing assessment 15cm**	Documented assessment	Internal assessment
21	**Usability evaluation**	Usability Study	IEC 62366-1

The device is cleared for use in Europe (CE certification no.2017847CE05). Feedback recorded from 16 clinical cases performed in 7 centers in Germany in April and May 2014 demonstrated that the subject device performs comparably with the secondary predicate and other legally marked devices and is safe and effective. The performance is identical with the primary predicate. No clinical testing is being submitted to support review of this 510(k) premarket notification.

VIII. CONCLUSIONS

Results demonstrate that the DuraSheath Introducer Sheath System performs identically with the primary predicate, comparably with the second predicate and other legally marketed devices, and is safe and effective. The DuraSheath Introducer Sheath System is substantially equivalent to the two predicates devices in terms of intended use, design and materials, technological characteristics, and principle of operation. Any differences between the subject device and the predicates do not raise any issues of safety or effectiveness.