September 30, 2025

Shanghai Draeger Medical Instrument Co., Ltd.
Guozhao Pan, RA
3#, No.229, Hupo Road Shanghai International Medical Zone
Shanghai, 201321
China

Re: K251669
Trade/Device Name: IBP transducer adapter cable, Argon/BD/Ohmeda, 2m;
IBP transducer adapter cable, Draeger 10-pin, 2m;
IBP transducer adapter cable, Draeger 7-pin, 2m;
IBP transd. adapter cbl, Abbott/Medex, Smiths/TranStar 2m;
IBP transducer adapter cable, Baxter/Edwards, 0.3m;
IBP transducer adapter cable, Baxter/Edwards, 2m;
IBP transducer adapter cable, Argon/BD/Ohmeda, 0.3m;
IBP transducer adapter cable, Draeger 10-pin, 0.3m;
IBP transducer adapter cable, Draeger 7-pin, 0.3m;
IBP transducer adapter cable, Utah Medical, 0.3m;
IBP transducer adapter cable, Utah Medical, 2m;
IBP transd. adapter cable, Abbott/Medex, Smiths/TranStar, 0.3m;
IBP transducer adapter cable, Codan/DPT, 0.3m;
IBP transducer adapter cable, Codan/DPT, 2m;
IBP transducer adapter cable, Codan/Xtrans, 0.3m
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: September 4, 2025
Received: September 4, 2025

Dear Guozhao Pan:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251669

Please provide the device trade name(s).

IBP transducer adapter cable, Argon/BD/Ohmeda, 2m
IBP transducer adapter cable, Draeger 10-pin, 2m
IBP transducer adapter cable, Draeger 7-pin, 2m
IBP transd. adapter cbl, Abbott/Medex, Smiths/TranStar 2m
IBP transducer adapter cable, Baxter/Edwards, 0.3m
IBP transducer adapter cable, Baxter/Edwards, 2m
IBP transducer adapter cable, Argon/BD/Ohmeda, 0.3m
IBP transducer adapter cable, Draeger 10-pin, 0.3m
IBP transducer adapter cable, Draeger 7-pin, 0.3m
IBP transducer adapter cable, Utah Medical, 0.3m
IBP transducer adapter cable, Utah Medical, 2m
IBP transd. adapter cable, Abbott/Medex, Smiths/TranStar, 0.3m
IBP transducer adapter cable, Codan/DPT, 0.3m
IBP transducer adapter cable, Codan/DPT, 2m
IBP transducer adapter cable, Codan/Xtrans, 0.3m

Please provide your Indications for Use below.

The reusable Dräger IBP adapter cables are intended to forward electrical signals from pressure transducers to Dräger Hemo devices (Pods).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Traditional 510(k)

IBP transducer adapter cables

Attachment 20

510k Summary

510(k) Premarket Notification Summary

Submitter:
Shanghai Draeger Medical Instrument Co., Ltd.
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Pudong New District Shanghai, 201321 Shanghai, China
Establishment's registration number: 3019545235

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Date prepared:
10 May 2025

Device Name:
Trade name:
IBP transducer adapter cable, Argon/BD/Ohmeda, 2m/ IBP transducer adapter cable, Draeger 10-pin, 2m/ IBP transducer adapter cable, Draeger 7-pin, 2m / IBP transducer adapter cable, Abbott/Medex, Smiths/TranStar 2m / IBP transducer adapter cable, Baxter/Edwards, 0.3m / IBP transducer adapter cable, Baxter/Edwards, 2m/ IBP transducer adapter cable, Argon/BD/Ohmeda, 0.3m / IBP transducer adapter cable, Draeger 10-pin, 0.3m / IBP transducer adapter cable, Draeger 7-pin, 0.3m / IBP transducer adapter cable, Utah Medical, 0.3m / IBP transducer adapter cable, Utah Medical, 2m / IBP transducer adapter cable, Abbott/Medex, Smiths/TranStar, 0.3m / IBP transducer adapter cable, Codan/DPT, 0.3m / IBP transducer adapter cable, Codan/DPT, 2m / IBP transducer adapter cable, Codan/Xtrans, 0.3m

Common name: IBP (invasive blood pressure) transducer adapter cables
Classification name: Patient transducer and electrode cable (including connector)
Regulation number: 21 CFR §870.2900

Product code: DSA
Class: II

Predicate device:

The features and functions of the proposed IBP transducer adapter cables are equivalent to the following previously cleared device(s):
IBP transducers interface cables, K162768, INTEGRAL PROCESS SAS, Class II

Device Description

This traditional 510(k) submission covers 15 distinct IBP transducer adapter cables [also referred to as IBP adapter cables] developed and manufactured by Shanghai Draeger Medical Instrument Co., Ltd., based in Shanghai, China. These devices are passive electrical conductors in the context of invasive blood pressure (IBP) monitoring used to transmit electrical signals acquired from an IBP transducer (not part of this submission) to an external IBP Module (Pod) within a patient monitoring system (not part of this submission). They do not modify the signal but convey it in an unchanged manner to the monitoring device.

The Pod is referring to the MPod- QuadHemo and Mcable- DualHemo.

Intended Use

The reusable Dräger IBP adapter cables are intended to forward electrical signals from pressure transducers to Dräger Hemo devices (Pods).
The following devices may be used:

- Dräger Infinity MPod - QuadHemo
- Dräger Infinity MCable - DualHemo

Environment of Use

1) This medical device is intended for hospital use only.
2) When storing or operating this medical device, observe the permissible ranges for ambient temperature and relative humidity.

   Ambient conditions

   -During storage and transport

Temperature	-20 to 60℃（-4 to 140 ℉）
Relative humidity	10 to 95%（non-condensing）
Ambient pressure	500 to 1060 hPa（7.3 to 15.4 psi）

   -During operation

Temperature	0 to 45℃（32 to 113℉）
Relative humidity	10 to 95%（non-condensing）
Ambient pressure	640 to 1060 hPa（9.3 to 15.4 psi）

3） IBP transducer adapter cable cannot be used in or in the proximity of MRI devices.

The product is not considered MRI safe.
4） IBP adapter cables cannot be used during radiography.

List of Consensus Standards

Standard Number and Version	Title
IEC 60601-1:2020 Edition 3.2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
IEC 60601-1-2 Edition 4.1 2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-34 Edition 3.0 2011-05	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
IEC TS 60601-4-2 Edition 1.0 2016-05	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
ISO 17664-2 First edition 2021-02	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices

Comparison to Predicate

Shanghai Draeger Medical Instrument Co., Ltd. concludes that IBP transducer adapter cables in Table 1 are substantially equivalent to the INTEGRAL PROCESS SAS IBP transducers interface cables (K162768).

Table 1 Comparison Table

Elements of Comparison	**Subject Device**	**Predicate Device**	**Comment**
Product Name	IBP transducer adapter cable	IBP transducers interface cables	--
Manufacturer	Shanghai Draeger Medical Instrument Co., Ltd.	INTEGRAL PROCESS SAS.	-
General Comparison			
510(k) Number	Applying	K162768	N/A
Device Classification	2	2	Same
Regulation Number	870.2900	870.2900	Same
Product Code	DSA	DSA	Same
Indications for Use	The reusable Dräger IBP adapter cables are intended to forward electrical signals from pressure transducers to Dräger Hemo device (Pods).	Integral-Process Medical Patient Cable and Leadwire Systems are intended to be used with various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes such as ECG, EKG, SpO2 and Blood Pressure equipment. They are solely intended to be used between the electrode in contact with the patient's skin and the recording/monitoring device. This cabling	Similar， the subject device and predicate device both serve the primary purpose of conducting signals, specifically from invasive blood pressure (IBP) transducer sets to patient monitoring devices. Despite any differences in the

Elements of Comparison	Subject Device	Predicate Device	Comment
		facilitates the conduction of signals between the patient and the monitoring device. Integral-Process Medical Patient Cable and Leadwire Systems are limited by the Indications for Use of the connected recording/monitoring device.	specific wording of the indications for use statement, the meaning remains the same. Therefore, the differences in wording are not critical to the intended use of the device and do not affect the safety and effectiveness of the device when used as labeled.
Usage	Reusable	Reusable	Same
Sterile	Not-sterile	Not-sterile	Same
Design /Appearance	IBP transducer adapter cables have various Transducer connectors (Yoke type: Utah 4 pin, for example) to connect with the Invasive Blood Pressure transducer and the other ends have a Pods connector (Molex 5 pin connector) to connect with the Drager Hemo Pods of the monitoring system.	Integral Process invasive blood pressure cable has various connectors (Yoke type: on the transducer side, instrument connector on the other side).	Similar, the specific monitor connector may slightly differ in its appearance. Both the subject and predicate devices are designed using similar components, including transducer connectors, bending reliefs, cables, and monitor connectors.

Elements of Comparison	Subject Device	Predicate Device	Comment
			The materials are fundamentally similar, utilizing copper wires as the primary material for signal transmission, wrapped with TPU for external insulation. Both, the subject device and predicate device, operate based on the same principle of passive signal conduction and do not require an external energy source, thereby maintaining operational equivalence. Despite minor differences in connector design, these variations do not alter the core technology or raise new concerns about the devices' safety and effectiveness.
Wire material	Shielded copper with TPU Jacket	Shielded & Unshielded Copper; medical grade TPU cable jacket with medical	Similar,

Elements of Comparison	Subject Device	Predicate Device	Comment
		grade PA overmolded connectors with integral strain relief.	the structure of the subject device is identical to that of the equivalent device. However, while the predicate device provides two material options, the subject device incorporates only one of these materials.
Cable Length	0.3m-2m	Various specified standard lengths	Different, the manufacturer has set up different length configurations based on the market demand of customers. However, this does not affect the performance and intended use of the product.
Patient Connection	non - patient - contacting Incidental contact with the user during normal operation may occur.	The leadwire is connected to the ECG or EKG electrodes placed at standard specified locations on the patient limbs and/or chest. There is no description of IBP cables.	Same, the predicate device does not come into direct contact with the patient during actual use; therefore, there is no specific description of

Elements of Comparison	Subject Device	Predicate Device	Comment
			the IBP cables in relation to anatomical sites.
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Same The newly introduced standard ISO 10993-23 serves as a replacement for the irritation testing protocols previously outlined in ISO 10993-10.
Electrical Safety and Performance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-34	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-34	Same

The indications for use and fundamental scientific technology are the same for both the subject device and the predicate devices. The differences in the design do not raise any different questions of safety and effectiveness.

Discussion of Non-clinical Testing

The following identified verification and validation activities necessary to establish substantial equivalence to the predicate device were carried out under well-established methods and the evidence is included in this 510(k) submission.

- Biocompatibility Testing
- Reprocessing/Cleaning/Disinfection
- Electrical function test
- Electrical Safety
- Electromagnetic Compatibility (EMC)

No human or animal clinical studies were submitted as part of this 510(k) Premarket Notification.

Conclusion

Based on the indications for use/intended use, technological characteristics, performance/nonclinical testing, and comparison to the predicate devices, the subject devices are substantially equivalent to the legally marketed predicate devices and raise no new safety and effectiveness questions compared to the predicate devices.

- END -