December 1, 2025

Drägerwerk AG & Co. KGaA
Jan Upmeier
Regulatory Affairs Manager
Moislinger Allee 53-55
Luebeck, SH 23542
Germany

Re: K252827
Trade/Device Name: IBP cables and IBP adapter cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: September 5, 2025
Received: September 5, 2025

Dear Jan Upmeier:

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,
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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.	K252827 ?
Please provide the device trade name(s). ?	
IBP cables and IBP adapter cables	
Please provide your Indications for Use below. ?	
The IBP cables and IBP adapter cables are intended to forward electrical signals from connected IBP pressure transducer sets to the patient monitor.	
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) ?

510(k) Premarket Notification Summary

Submitter: Drägerwerk AG & Co. KGaA
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Date prepared: 3 November 2025

Device Name:

Trade name:	IBP cables and IBP adapter cables
Regulation description:	Patient transducer and electrode cable (including connector)
Regulation number:	21 CFR §870.2900
Product code:	DSA
Class:	II

Predicate device: IBP transducers interface cables, cleared via K162768, INTEGRAL PROCESS SAS. Class II.

Device Description

This traditional 510(k) submission comprises six distinct IBP cables and IBP adapter cables [IBP (adapter) cables] to transmit electrical signals acquired from an IBP transducer to the Draeger Vista 300 Patient Monitor:

Table 1: IBP adapter cable Versions

Part No.	Designation
2606488	IBP cable Becton Dickinson
2606489	IBP cable Edwards
2606490	IBP cable Abbott, Medex
2606491	IBP cable Utah
2607558	IBP Adapter Cable Draeger 7pin
2607559	IBP Adapter Cable Draeger 10pin

The subject devices are passive electrical conductors in the context of invasive blood pressure (IBP) monitoring and do not modify the signal but convey it in an unchanged manner to the Draeger Vista 300 Patient Monitor.

Indications for Use

The IBP cables and IBP adapter cables are intended to forward electrical signals from connected IBP pressure transducer sets to the patient monitor.

Environment of Use

Operating the medical device under unsuitable ambient conditions may compromise its performance.

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

Table 2: Ambient conditions

During operation	
Temperature:	0°C to 45°C (32 to 113°F)
Ambient pressure:	640 to 1060hPa (9.3 to 15.4 psi)
Relative humidity:	10% to 95%, non-condensing
During storage and transport	
Temperature:	-20°C to 60°C (-4 to 140°F)
Ambient pressure:	500 to 1060hPa (7.3 to 15.4 psi)
Relative humidity:	10% to 95%, non-condensing

Comparison to Predicate

Drägerwerk AG & Co KGaA concludes that IBP cables and IBP adapter cables in Table 1 are substantial equivalent to the INTEGRAL PROCESS SAS's product IBP transducers interface cables (K162768).

Table 1 Comparison Table

Elements of Comparison	Subject Device	Predicate Device	Comment
Product Name	IBP cables and IBP adapter cables	IBP transducers interface cables	--
510(k) Number	this application	K162768	--
Indications for Use	The IBP cables and IBP adapter cables are intended to forward electrical signals from connected IBP pressure transducer sets to the patient monitor.	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 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.	**Similar**
Usage	Reusable	Reusable	**Same**
Sterile	Non-sterile	Non-sterile	**Same**
Design /Appearance	Invasive Blood Pressure cables with various connectors (Transducer connector on the transducer side, Monitor connector on the other side.	Integral Process invasive blood pressure cable has various connectors (Yoke type: on the transducer side, instrument connector on the other side.	**Similar**
Signal conduction principle	passive	passive	**Same**
Wire material	Shielded Copper; medical grade TPU cable jacket with medical grade TPU overmolded connectors with integral strain relief.	Shielded & Unshielded Copper; medical grade TPU cable jacket with medical grade PA overmolded connectors with integral strain relief.	**Similar**
Cable Length	3.8 m	Various specified standard lengths	**Different**

The indications for use and fundamental scientific technology are the same for the proposed and predicate devices.

Performance Data

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
- Mechanical testing
- Electrical function test
- Electrical Safety and Electromagnetic Compatibility (EMC)

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

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted for IBP cables and IBP adapter cables. The devices comply with the IEC 60601-1 for basic safety and performance and the IEC 60601-1-2 standard for EMC.

Further Performance Testing

To demonstrate performance and functionality, IBP cables and IBP adapter cables were tested and meet all applicable requirements of the following standards:

- IEC 60601-2-34: Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
- TS 60601-4-2: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- ISO 17664-2: 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

Biocompatibility Testing

All materials used in the fabrication of the IBP cables and IBP adapter cables and also the completed products were evaluated through biological qualification safety tests as outlined in ISO 10993-1 “Biological Evaluation of Medical Devices”. These materials were also tested in accordance with industry recognized test methods and were found to be acceptable for the intended use. The following tests were performed:

- Cytotoxicity according to ISO 10993-5
- Sensitization according to ISO 10993-10
- Irritation according to ISO 10993-10

List of Consensus Standards

Standard Number	Standards Title	FDA Recognition No. + date
IEC 60601-1 Edition 3.2 2020-08	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-49 04/03/2023
IEC 60601-1-2 Edition 4.1 2020-09	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36 12/21/2020
IEC 60601-2-34 :2024	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment	/
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-258 01/14/2019
TS 60601-4-2 Edition 1.0 2024-03	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	19-50 05/29/2024
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	14-579 05/30/2022
ISTA 3A 2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less	5-126 07/06/2020

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.

- END -