October 7, 2024

DEKA Research and Development Corporation
Paul Smolenski
Director of Regulatory Affairs
340 Commercial Street
Manchester, New Hampshire 03101

Re: K242693
Trade/Device Name: DEKA Infusion System, DEKA Administration Set
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LDR, FPA
Dated: September 5, 2024
Received: September 9, 2024

Dear Paul Smolenski:

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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K242693

Device Name
DEKA Infusion System, DEKA Administration Set

Indications for Use *(Describe)*
The DEKA Infusion System is indicated for continuous delivery of general maintenance fluids and supported antibiotics to adult patients through a peripheral intravenous (IV) site under the supervision of a qualified clinician.

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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DEKA Research & Development Corp.

K242693 510(k) Summary

This 510(k) Summary of safety and effectiveness information is prepared in accordance with the requirements of CFR Part 807.92.

Submitter Information

510(k) Sponsor	DEKA Research and Development 340 Commercial Street Manchester NH, 03101
Contact Person(s)	Paul Smolenski (primary), Rhianne Tallarico (secondary) Regulatory Affairs Phone: (603) 669-5139 Fax: (603) 624-0573 Email: psmolenski@dekaresearch.com, rtallarico@dekaresearch.com
Date Prepared	September 5, 2024

Proposed Device(s)

Common/Usual Name:	Infusion Controller
Trade/Proprietary Name:	DEKA Infusion System
Classification Name:	Controller, Infusion, Intravascular, Electronic
Device Classification:	880.5725
Product Code:	LDR
Class:	II
Device Panel:	General Hospital

Common/Usual Name:	Intravascular Administration Set
Trade/Proprietary Name:	DEKA Administration Set
Classification Name:	Set, Administration, Intravascular
Device Classification:	880.5440
Product Code:	FPA
Class:	II
Device Panel:	General Hospital

Predicate Device(s)

The subject device is a modified version of the predicate DEKA Infusion System, cleared under K232316 on March 1, 2024. The subject device is substantially equivalent to the predicate DEKA Infusion System.

Device Description

The subject device is a modified version of the predicate DEKA Infusion System. Updates have been made to the predicate device software to increase the maximum programmable flow rate (from 300 to 600 mL/h), update the labeling to reflect the increased maximum programmable flow rate and update the performance of tilt angle detection. The administration set is unchanged.

DEKA Infusion System

The DEKA Infusion System, comprised of the DEKA Infusion Controller and DEKA Administration Set, is a gravity-based infusion controller. The Infusion Controller uses a camera to view drop formation in an Administration Set Drip Chamber in order to measure flow rate. During an infusion, the Infusion Controller can adjust the position of the Flow Control Valve (FCV) as necessary against the DEKA Administration Set to maintain the desired flow rate without user intervention.

DEKA Administration Set

The DEKA Administration Set is a single-use, non-DEHP intravascular administration set provided sterile. It is compatible with the DEKA Infusion Controller or can be used as a stand-alone administration set for performing manual gravity infusions.

Indications for Use

DEKA Infusion System

The DEKA Infusion System is indicated for continuous delivery of general maintenance fluids and supported antibiotics to adult patients through a peripheral intravenous (IV) site under the supervision of a qualified clinician.

Contraindications

The DEKA Infusion System is not indicated for delivery of high-alert medications, blood, and blood products. The DEKA Infusion System is not indicated for use with pediatric or neonatal patients. The DEKA Infusion System is not indicated for use with a pressurized infusate source. The DEKA Infusion System is not indicated for use during transport.

The DEKA Infusion System is not indicated for use with patients who have certain pre-existing medical conditions that put them at risk of complications from a gravity infusion. A list of conditions that would prohibit the use of the DEKA Infusion System can be found below.

- Congestive Heart Failure
- A combination of Eisenmenger's Syndrome and Patent Foramen Ovale
- Acute Myocardial Infarction
- Acute Respiratory Failure
- Acute Respiratory Distress Syndrome
- Acute Hemorrhage or Hemorrhagic Shock
- Other critical illnesses
- Renal Failure/Patients on dialysis
- Patients on fluid restrictions
- Patients in need of aggressive fluid resuscitation

DEKA Administration Set

The DEKA Administration Set is indicated for gravity administration of general maintenance fluids and supported antibiotics approved for peripheral intravenous (IV) infusion to adult patients under the supervision of a qualified clinician. The DEKA Administration Set is indicated for single patient use only. The DEKA Administration Set is not indicated for administration of high-alert medications, blood, and blood products.

The DEKA Administration Set is compatible with the DEKA Infusion Controller or can be used as a stand-alone administration set for performing manual gravity infusions.

Substantial Equivalence Discussion

The table below compares the characteristics of the subject device to the predicate device.

Characteristic	**Predicate Device – K232316**	**Subject Device**	**Equivalence**
General			
Device Classification Regulation and Product Code	21 CFR 880.5725 Product Code: LDR	21 CFR 880.5725 Product Code: LDR	No change
Class	II	II	No change

Characteristic	Predicate Device – K232316	Subject Device	Equivalence
Intended Use	The DEKA Infusion System, comprised of the DEKA Infusion Controller and the DEKA Administration Set, is intended for continuous delivery through a peripheral intravenous (IV) site of general maintenance fluids and supported antibiotics under the supervision of a qualified clinician. The DEKA Infusion System is not intended to administer high-alert medications, blood, and blood products.	The DEKA Infusion System, comprised of the DEKA Infusion Controller and the DEKA Administration Set, is intended for continuous delivery through a peripheral intravenous (IV) site of general maintenance fluids and supported antibiotics under the supervision of a qualified clinician. The DEKA Infusion System is not intended to administer high-alert medications, blood, and blood products.	No change
Prescription or Over the Counter (OTC)	Prescription	Prescription	No change
Intended Patient Population	Adults	Adults	No change
Environment of Use	Under supervision of a qualified clinician	Under supervision of a qualified clinician	No change
Compatible Administration Set	DEKA Administration Set, 20 drop/mL (non-DEHP)	DEKA Administration Set, 20 drop/mL (non-DEHP)	No change
Supported Infusates	Maintenance Fluids Antibiotic – Aminoglycosides Antibiotic – Carbapenems Antibiotic – Cephalosporins Antibiotic – Fluoroquinolone Antibiotic – Nitroimidazole Antibiotic – Penicillin	Maintenance Fluids Antibiotic – Aminoglycosides Antibiotic – Carbapenems Antibiotic – Cephalosporins Antibiotic – Fluoroquinolone Antibiotic – Nitroimidazole Antibiotic – Penicillin	No change
Applicable Standards			
Applicable Standards	ISO 14971 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 62304	ISO 14971 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 62304	No change

Characteristic	Predicate Device – K232316	Subject Device	Equivalence
Environmental Specifications			
Operating Environment	Temperature: 15 °C to 40 °C Relative Humidity: 15 % to 90%, non-condensing Altitude: -300 m to 3000 m	Temperature: 15 °C to 40 °C Relative Humidity: 15 % to 90%, non-condensing Altitude: -300 m to 3000 m	No change
Storage Environment	Temperature and Relative Humidity: -25 to 5 °C, with uncontrolled humidity 5 to 35 °C, with up to 90% RH, non-condensing >35 to 70 °C, with a water vapor partial pressure ≤ 50 hPa Altitude: -300 m to 3000 m	Temperature and Relative Humidity: -25 to 5 °C, with uncontrolled humidity 5 to 35 °C, with up to 90% RH, non-condensing >35 to 70 °C, with a water vapor partial pressure ≤ 50 hPa Altitude: -300 m to 3000 m	No change
Specified Ingress Protection rating for Intended Use Environment	IP42	IP42	No change
Physical Characteristics			
Weight	< 450 g (not including power supply and primed Administration Set)	< 450 g (not including power supply and primed Administration Set)	No change
Physical Dimension Requirements	< 5.11” x 5.11” x 2.55”	< 5.11” x 5.11” x 2.55”	No change
Number of Channels	1	1	No change
Power Requirements	100-127/220-240 V AC, Rechargeable Lithium Battery	100-127/220-240 V AC, Rechargeable Lithium Battery	No change
Battery Life	A fully charged new battery will provide at least 8 hours of battery life during normal operation.	A fully charged new battery will provide at least 8 hours of battery life during normal operation.	No change
Performance Characteristics			
Control Mechanism	Video camera and vision processing system with a flow control valve	Video camera and vision processing system with a flow control valve	No change

Characteristic	Predicate Device – K232316	Subject Device	Equivalence
Programmable Flow Rate Range	10 to 300 mL/h in 1 mL/h increments	10 to 600 mL/h in 1 mL/h increments	Different
Flow Rate Accuracy	± 10% nominally ± 25% under environmental limits of normal use	± 10% nominally ± 25% under environmental limits of normal use	No change
Volume to be Infused (VTBI)	10 mL to 1300 mL in 1 mL increments	10 mL to 1300 mL in 1 mL increments	No change
Time to reach target Flow Rate	< 5 minutes	< 5 minutes	No change
Time to detect an Occlusion	< 5 minutes	< 5 minutes	No change

Programmable Flow Rate Range: The programmable flow rate range of the subject device has been verified through formal testing to meet acceptance criteria and does not raise new or different questions of safety or effectiveness. Increasing the maximum programmable flow rate from 300 to 600 mL/h does not introduce any new risks. The supported infusates remain applicable to the subject system at this range.

Characteristic	Predicate Device – K232316	Subject Device	Equivalence
Alarm Conditions			
Internal System Fault Conditions	• Low Battery • Timeout • Interruption of Infusion • Tilt • Shake • Camera Blocked • Invalid/Missing Administration Set • Prime Level • Mean Flow Rate Error • Cannot Start Flow • No Flow • Streaming (Free Flow) • Retrograde Flow • End of Infusion	• Low Battery • Timeout • Interruption of Infusion • Tilt • Shake • Camera Blocked • Invalid/Missing Administration Set • Prime Level • Mean Flow Rate Error • Cannot Start Flow • No Flow • Streaming (Free Flow) • Retrograde Flow • End of Infusion	No change

Performance Data

Formal performance testing was conducted on all areas of the subject device that are impacted by its changes with respect to the predicate device. Predicate test methodologies were used to test the subject device. Performance data was used to establish substantial equivalence to the predicate device in terms of safety and effectiveness. The following areas of the system were tested.

- Flow Rate Accuracy
- Vision System Performance
- Stopping Flow
- Device Handling Alarms

All tests met acceptance criteria.

Animal and Clinical Studies

No animal study or clinical trial data was obtained in support of this submission.

Design Control

The DEKA Infusion System was specified and developed by DEKA. DEKA complies with the FDA Quality System Regulation as specified in 21 CFR 820, as well as ISO 13485:2016.

Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The subject system is substantially equivalent to the DEKA Infusion System cleared under K232316 with respect to the indications for use, treatment method, and technological characteristics.