March 1, 2024

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

Re: K232316
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: January 31, 2024
Received: February 1, 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.

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.

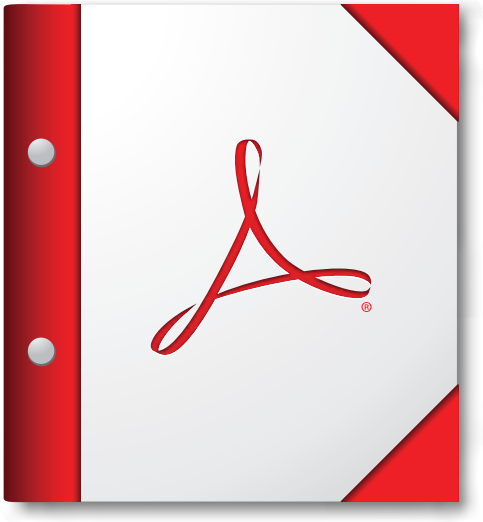
For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant 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

Enclosure



For the best experience, open this PDF portfolio in Acrobat X or Adobe Reader X, or later.

Get Adobe Reader Now!

DEKA Research & Development Corp.

510(k) Summary

This 510(k) Summary of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92.

Submitter Information

510(k) Sponsor	DEKA Research & Development 340 Commercial Street Manchester, NH 03101
Contact Person(s)	Paul Smolenski (primary), Lauren Blake (secondary) Regulatory Affairs Phone: (603) 669-5139 Fax: (603) 624-0573 psmolenski@dekaresearch.com, lblake@dekaresearch.com
Date Prepared	August 2, 2023

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)

DEKA Infusion System

The DEKA Infusion System is substantially equivalent to the DEKA Volumetric Infusion Controller, which was previously cleared under premarket application K153760 on October 3, 2016.

The DEKA Infusion System has a VTBI functionality that is substantially equivalent to that of the reference device, the QCore Sapphire Infusion Pump cleared on November 19, 2020 under premarket notification K192860.

DEKA Administration Set

The DEKA Administration Set is substantially equivalent to the Zyno Medical Administration Set, which was previously cleared under premarket application K120685 on September 7, 2012.

Device Description

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 tables below compare the characteristics of the subject devices to their respective predicate devices.

DEKA Infusion System

Characteristic	Predicate Device – DEKA Volumetric Infusion Controller (K153760)	Subject Device – DEKA Infusion System	Equivalence
General			
Device Classification Regulation and Product Code	21 CFR 880.5725 Product Code: LDR	21 CFR 880.5725 Product Code: LDR	Identical
Class	II	II	Identical
Intended Use	The Volumetric Infusion Controller is intended for the delivery of general maintenance fluids and non- critical antibiotics to adult patients using gravity infusion in a clinical setting by a trained medical professional. The device is not intended to administer critical fluids, including high-risk medications.	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.	Equivalent
Prescription or Over the Counter (OTC)	Prescription	Prescription	Identical

Characteristic	Predicate Device – DEKA Volumetric Infusion Controller (K153760)	Subject Device – DEKA Infusion System	Equivalence
Intended Patient Population	Adults	Adults	Identical
Environment of Use	In a clinical setting by a trained medical professional	Under supervision of a qualified clinician	Equivalent
Compatible Administration Set	Baxter Healthcare 10 drop/mL administration set: • 1C8109S (DEHP) • 2H8401 (non-DEHP) Both administration sets are FDA-cleared.	DEKA Administration Set, 20 drop/mL (non-DEHP)	Equivalent
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	Identical
Environmental Specifications			
Operating Environment	Temperature: 15 °C to 30 °C Relative Humidity: 20 % to 85%, non-condensing Altitude: 0 m to 2000 m	Temperature: 15 °C to 40 °C Relative Humidity: 15 % to 90%, non-condensing Altitude: -300 m to 3000 m	The subject device's wider operating environment is equivalent in safety and effectiveness, as supported through performance testing.

Characteristic	Predicate Device – DEKA Volumetric Infusion Controller (K153760)	Subject Device – DEKA Infusion System	Equivalence
Specified Ingress Protection rating for Intended Use Environment	IPX2	IP42	The subject device's higher ingress protection rating is supported through performance testing.
Physical Specifications and Electrical Power Requirements			
Weight	< 600 g (not including power supply and IV administration set)	< 450 g (not including power supply and primed Administration Set)	Similar weight
Physical Dimension Requirements	3.94" x 2.76" x 7.09"	< 5.11" x 5.11" x 2.55"	Similar dimensions
Power Requirements	100-127/220-240 V AC, Rechargeable Lithium Battery	100-127/220-240 V AC, Rechargeable Lithium Battery	Identical
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	Identical
Flow Rate Accuracy	± 10% nominally ± 25% under environmental limits of normal use	± 10% nominally ± 25% under environmental limits of normal use	Identical
Flow Rate Range	10 mL/hr to 300 mL/hr in 1 mL/hr increments	10 mL/hr to 300 mL/hr in 1 mL/hr increments	Identical

Characteristic	Predicate Device – DEKA Volumetric Infusion Controller (K153760)	Subject Device – DEKA Infusion System	Equivalence
Volume to be Infused (VTBI)	None	10 mL to 1300 mL in 1 mL increments	VTBI is not considered new technology. This functionality is equivalent to that of the reference device (K192860) and is supported through performance testing.
Time to reach target Flow Rate	< 5 minutes	< 5 minutes	Identical
Time to detect an Occlusion	< 65 seconds	< 5 minutes	The subject device has a longer time to detect an Occlusion. Equivalent safety and effectiveness was demonstrated through risk management and performance testing.
Alarm Conditions			
Internal System Fault Conditions	Yes	Yes	Equivalent
Low Battery	Yes	Yes	Equivalent
Timeout	Yes	Yes	Equivalent
Interruption of Infusion	Yes	Yes	Equivalent
Tilt	Yes	Yes	Equivalent
Shake	Yes	Yes	Equivalent
Camera Blocked	Yes	Yes	Equivalent
Invalid/Missing Administration Set	Yes	Yes	Identical

Characteristic	Predicate Device – DEKA Volumetric Infusion Controller (K153760)	Subject Device – DEKA Infusion System	Equivalence
Administration Set Prime Level	Yes	Yes	Equivalent
Mean Flow Rate Error	Yes	Yes	Identical
Cannot Start Flow	Yes	Yes	Equivalent
No Flow	Yes	Yes	Equivalent
Streaming (Free Flow)	Yes	Yes	Equivalent
Retrograde Flow	Yes	Yes	Equivalent
End of Infusion	No	Yes	Equivalent to Reference Device (K192860)

DEKA Administration Set

Characteristic	Predicate Device – Zyno Medical Administration Set (K120685)	Subject Device – DEKA Administration Set	Equivalence
Device Classification Regulation and Product Code	21 CFR 880.5440 Product Code: FPA	21 CFR 880.5440 Product Code: FPA	Identical
Class	II	II	Identical

Characteristic	Predicate Device – Zyno Medical Administration Set (K120685)	Subject Device – DEKA Administration Set	Equivalence
Intended Use	Zyno Medical Administration Set is a device used to administer fluids from a container to a patient's vascular system through a needle or a catheter inserted into a vein.	The DEKA Administration Set is intended 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 intended for single patient use only. The DEKA Administration Set is not intended 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.	Equivalent
Sterility Assurance Level (SAL)	Labeled as sterile (equivalent to an SAL of 10e-6)	Labeled as sterile (equivalent to an SAL of 10e-6)	Identical
Applicable Standards	• ISO 8536-4 • ISO 10993	• ISO 8536-4 • ISO 10993	Identical
Drop Size	20 drops/mL	20 drops/mL	Identical

Characteristic	Predicate Device – Zyno Medical Administration Set (K120685)	Subject Device – DEKA Administration Set	Equivalence
Components	• Tubing • Protective spike cap • Drip chamber with spike • Air vent • Slide clamp • Pinch clamp • Roller clamp • Male Luer lock • Protective Luer lock cap • 0.22 or 1.2 micron filter • Back-check valve • Needleless Y-site	• Tubing • Protective spike cap • Drip chamber with spike • Air vent • Slide clamp • Roller clamp • **Flow Control Insert** • Male Luer lock • Protective Luer lock cap	The subject device has a simpler list of components, which does not impact safety or effectiveness. The subject device also includes a multi-lumen Flow Control Insert, which has been verified for safety and effectiveness through performance testing.
Fluid Path Material	Non-DEHP PVC	Non-DEHP PVC, medical grade silicone	The subject device has a multi-lumen flow control insert made of medical grade silicone, which is a material typically used in industry. The safety and effectiveness of the Flow Control Insert is supported through performance testing.
Patient Connector Type	Male Luer	Male Luer	Identical
Single use?	Yes	Yes	Identical
Priming Volume (approx.)	18 mL	13 mL	Equivalent

Performance Data

Performance testing was conducted in order to verify and validate each subject device for its respective intended use, and to establish substantial equivalence to the respective predicate device in terms of safety and effectiveness.

The FDA Guidance Documents, *Infusion Pumps Total Product Life Cycle*, issued December 2, 2014, and *Intravascular Administration Sets Premarket Notification Submissions [510(k)]*, issued July 11, 2008 were followed.

DEKA Infusion System

Device Performance	The following functional areas were evaluated: • Flow rate accuracy (per AAMI TIR101:2021) • Ability to stop flow • Response to Alarm conditions • Performance after shipping or storage, and at limits of operating conditions • Infusion Controller/Administration Set integration • Durability and reliability • Battery performance
Software and Cybersecurity	The subject device is considered to require an "Enhanced Documentation Level" per the 2023 guidance (equivalent to a "Major" level of concern in the 2005 guidance). Software and Cybersecurity testing was conducted per ANSI AAMI IEC 62304:2006/A1:2016 and the following FDA Guidance Documents: • *Content of Premarket Submissions for Device Software Functions*, issued June 14, 2023 • *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued May 11, 2005 • *Off-The-Shelf Software Use in Medical Devices*, issued September 27, 2019 • *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, issued October 2, 2014 • *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*, issued April 8, 2020 • *Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act*, issued March 30, 2023
Human Factors	The human factors validation followed the FDA Guidance Document, *Applying Human Factors and Usability Engineering to Medical Devices*, issued February 3, 2016, and the following standards: • IEC 60601-1-6:2020 • ANSI AAMI IEC 62366-1:2015+A1:2020

Reprocessing	Testing followed the FDA Guidance Document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, issued March 17, 2015.
Biocompatibility	Testing followed the FDA Guidance Documents, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, issued September 4, 2020, and ANSI AAMI ISO 10993-1:2018.
Electrical Safety	Per IEC 60601-1:2020
EMC	Per IEC 60601-1-2:2020
Alarms	Per IEC 60601-1-8:2020

DEKA Administration Set

Biocompatibility	Testing followed the FDA Guidance Document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, issued September 4, 2020 and ANSI AAMI ISO 10993-1:2018.
Sterility	Testing followed: • FDA Guidance Document, *Intravascular Administration Sets Premarket Notification Submissions [510(k)]*, issued July 11, 2008 • FDA Guidance Document, *and Review of Sterility Information in Premarket Notification [510(k)] Submissions for Devices Labeled as Sterile*, issued January 21, 2016 • ISO 11135:2014 • ISO 11607-1:2019
Device Performance	Testing was conducted per ISO 8536-4:2019. In addition, the following functional areas were evaluated: • Performance after shipping or storage, and at limits of operating conditions • Infusion Controller/Administration Set integration

Animal and Clinical Studies

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

Design Control

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

Conclusion

DEKA Infusion System

The DEKA Infusion System is substantially equivalent to the DEKA Volumetric Infusion Controller, cleared under premarket application K153760 on October 3, 2016. The differences summarized in this submission do not raise different questions of safety and effectiveness. The performance of the device is supported by DEKA's design control process which included non-clinical testing and risk management activities.

DEKA Administration Set

The DEKA Administration Set is substantially equivalent to the Zyno Medical Administration Set, cleared under premarket application K120685 on September 7, 2012. The differences summarized in this submission do not raise different questions of safety and effectiveness. The performance of the device is supported by DEKA's design control process which included non-clinical testing and risk management activities.