DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 3, 2016

DEKA Research & Development
Mr. Roger Leroux
Regulatory Affairs Project Manager
340 Commercial St.
Manchester, New Hampshire 03101

Re: K153760
Trade/Device Name: Volumetric Infusion Controller
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LDR
Dated: September 1, 2016
Received: September 2, 2016

Dear Mr. Roger Leroux:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,


Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K153760

Device Name
Volumetric Infusion Controller

Indications for Use *(Describe)*
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.

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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**510(K) SUMMARY**
**K153760**

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR 807.92.

## Submitter's Information


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**Date of Preparation** December 28, 2015

## Device Information

| | |
|---|---|
| Common/Usual Name: | Controller, Infusion, Intravascular, Electronic |
| Trade/Proprietary Name: | Volumetric Infusion Controller |
| Regulation Number: | 21 CFR 880.5725 |
| Regulation Name: | Infusion Pump |
| Regulatory Class: | Class II |
| Product Code: | LDR |
| Device Panel: | General Hospital |

## Predicate Device

The Volumetric Infusion Controller is substantially equivalent to the DEKA Jr. Volumetric Infusion Controller, which was previously cleared under application K863204.

## Device Description

The Volumetric Infusion Controller (VIC) is a gravity-based electronic infusion controller relying on head height to provide the delivery pressure necessary to meet the target infusion delivery rates. The drip chamber of an administration set is monitored by a vision system for drop growth. This information is used to provide feedback to the flow control valve to establish and maintain the target flow-rate without user intervention.

The device is capable of operating from wall power or on battery power. The VIC comes with an AC power supply (120V or 240V). When unplugged, the device is capable of running an infusion for more than 8 hours powered by the internal rechargeable battery. The device also has a second battery powering a safety system capable of stopping the infusion and alarming in the case of a sudden power failure.

**Indications for 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.

**Technological Characteristics**

The Volumetric Infusion Controller (VIC) has similar technological characteristics as compared to the predicate device. Similar to the DEKA Jr. predicate device, the VIC is a drop counter paired with a clamp that allows for the control of flow. Both devices operate by counting drops and ensuring that they are falling at the correct rate to achieve the desired flow rate. The predicate device uses “beam break” technology to determine when a drop had fallen whereas the VIC uses a video camera and vision processing to monitor the drop formation and detect drops falling. Beam break uses two beams of known width and known distance apart and uses the time period these beams are broken to determine the height of the drop, which is used to estimate the actual size of the drop. The VIC method is robust as it is less susceptible to interference from splashing. The VIC vision system uses similar algorithms to make the distinction between drops falling from the spout in the drip chamber and splashes of fluid adhering to the sides of the drip chamber. In addition, by watching the drop form, the VIC can determine if drops are forming quickly enough to achieve the desired flow rate between drops falling providing more accurate and more reactive control especially at low flow rates where the drop rate can be as long as one drop per 36 seconds.

Risk analysis has been completed and potential hazards associated with the proposed device have been identified and mitigated. All potential risks were deemed acceptable after mitigation.

## Comparison to Predicate Device

| Characteristic | Predicate (DEKA Jr.) (K863204) | Proposed (Volumetric Infusion Controller) (K153760) | Assessment of Difference |
|---|---|---|---|
| **General Characteristics** | | | |
| Intended Use | Electronic infusion controller designed to regulate the infusion of a wide variety of fluids where gravity provides adequate head pressure to achieve the desired flow rate. | 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. | Although the intended use for the proposed device has been modified to include categories of fluids to be used with the device, intended users, and intended environment, both devices are indicated for use for the purpose of controlling delivery of fluids using gravity infusion. Therefore, we believe that the differences in the indications for use do not raise new questions of safety or effectiveness. |
| Drop counter | Beam break technology | Video camera and vision processing | The predicate and proposed devices are both drop counters paired with a clamp that allows for the control of flow. The difference in the method for counting drops has been modified in the proposed device based on current technology. In addition to counting drops, the proposed device also monitors the drop formation and detects drops falling. This difference between the predicate and proposed device does not raise safety or effectiveness questions. |
| Volumetric | Yes | Same | N/A |
| Disposable to be used with device | Dedicated IV administration set | Baxter Healthcare 10 drop/mL<br>• 1C8109S (DEHP)<br>• 2H8401 (non-DEHP) | N/A |
| **System Performance** | | | |
| Volumetric Delivery accuracy | ± 10% | ± 10% | N/A |
| Flow rate range (for 10 drop/mL set) | 30-500 mL/hr | 10-300 ml/hr | No new associated risk. |
| Flow rate range (for 60 drop/mL set) | 10-250 mL/hr | Not applicable – device is only compatible with 10 drop/mL IV administration sets. | N/A |

| | | | |
|---|---|---|---|
| Time to target | Less than 5 minutes | Same | N/A |
| Operating duration | One IV administration set change | Up to 72 hours with a single IV administration set. | N/A - Assumed that the operation duration for the predicate device based on one IV administration set change was 72 hours. |
| **Environmental Requirements** | | | |
| Operating temperature range | 10C to 40C | 15C to 30C | No new associated risk. |
| Operating non-condensing humidity range | 5% to 95% | 20% to 85% | No new associated risk. |
| Operating altitude range | Unknown | Sea level to 2000m | Operating altitude for the predicate device not known. |
| **Physical Specification and Electrical Power Requirements** | | | |
| Weight | <340grams | <600grams (not including power supply and IV administration set) | No new associated risk. |
| Physical Size | 2" x 2.5" x 6" | 3.94" x 2.76" x 7.09" | No new associated risk. |
| Power Supply | 6.25 VDC, 5 AA cells | 100-127/220-240 VAC, Rechargeable Lithium Battery | No new associated risk. |
| **Alarms** | | | |
| Air in line | No | Same | N/A |
| Low battery | Yes | Same | N/A |
| Flow rate error | Yes | Same | N/A |
| Door open | Yes | Same | N/A |
| Drop sensor | Yes | Same | N/A |
| Occlusion | Yes | Same | N/A |
| Invalid IV Set | No | Yes | N/A |
| Reverse flow | No | Yes | N/A |
| Stream | No | Yes | N/A |
| No flow | No | Yes | N/A |

The VIC and the predicate device are both intended for use for the purpose of controlling delivery of fluids using gravity infusion. The modification of the indications for use of the VIC from the predicate to include categories of fluids to be used with the device, intended users, and intended environment do not adversely affect the performance of the VIC.

The method for counting drops has been modified in the proposed device based on current technology. The VIC proposed device uses a video camera and vision processing to monitor the drop formation and detect drops falling. The VIC method is robust as it is less susceptible to interference from splashing. The vision system uses similar algorithms to make the distinction between drops falling from the spout in the drip chamber and splashes of fluid adhering to the sides of the drip chamber. Based on demonstrable evidence provided in this 510(k), the device differences described within this submission do not affect the intended use, the fundamental technology or operating principles of the device, or raise safety or effectiveness issues. The changes to the technology allow for a robust system for monitoring and controlling flow rate.

**Performance Data**

The following performance data are provided in support of the substantial equivalence determination.

- Flow rate accuracy – Conducted in accordance with IEC 60601-2-24:2012 under three test conditions.

| Condition | Acceptance Criteria | Test Results | Conclusion |
|---|---|---|---|
| Minimum 72 hour infusion at 10 mL/h and head height within operating range | The second hour is within ±20% of the programmed flow rate | -1.00 to -2.00% | Pass |
| | The last hour of the infusions are within ±20% of the programmed flow rate | -0.80 to -1.80% | |
| Minimum 2 hour infusion at 25 mL/h and a head height simulated negative back pressure | The second hour is within ±20% of the programmed flow rate | -0.40 to -2.93% | Pass |
| 1L infusion at 300 mL/h and a head height within operating range | The second hour is within ±20% of the programmed flow rate | 5.56 to 6.42% | Pass |
| | The last hour of the infusions are within ±20% of the programmed flow rate | 5.33 to 6.64% | |

- Maintenance of set flow rate despite changes in head height – Conducted under worst case conditions using the accuracy calculation method of IEC 60601-2-24:2012 at two flow rates (10 and 300 mL/h) with increasing (50 to 200cm) and decreasing head heights (200 to 50cm).

| Condition | Acceptance Criteria | Test Result | Conclusion |
|---|---|---|---|
| Increasing head height (50 to 200cm) | • The device continues infusing and the accuracy does not exceed ±25%; or<br>• The device alarms | At 10mL/hr:<br>-7.03 to -9.87%<br>At 300mL/hr:<br>6.23 to 6.27%<br>(1 device alarmed) | Pass |
| Decreasing head height (200 to 50cm) | • The device continues infusing and the accuracy does not exceed ±25%; or<br>The device alarms | At 10mL/hr:<br>-10.57 to -13.17%<br>At 300mL/hr:<br>4.01%<br>(2 devices alarmed) | Pass |

- Reliability analysis – Tested as Mean Time Between Failures (MTBF). Devices are setup in nominal operating conditions and are continuously infusing solutions at flow rates that are changed each time the solution is resupplied. Between infusions, the devices are cleaned and disinfected according to the Instructions for Use. The total infusion time and the number of alarms are recorded over the course of the test.

<table>
<tr><th>Acceptance Criteria</th><th>Test Result</th><th>Conclusion</th></tr>
<tr><td>The devices performed the minimum number of infusion hours for the associated number of failures as shown in the table below
<table>
<tr><th>Number of Failures</th><th>Number of Uses</th><th>Number of Hours</th></tr>
<tr><td>0</td><td>422</td><td>7596</td></tr>
<tr><td>1</td><td>712</td><td>12816</td></tr>
<tr><td>2</td><td>974</td><td>17532</td></tr>
<tr><td>3</td><td>1223</td><td>22014</td></tr>
<tr><td>4</td><td>1463</td><td>26334</td></tr>
</table>
</td><td>In order to pass with zero failures the number of infusion hours to establish MTBF ≥6 months with 90% confidence would need to be ≥7596 hours. The actual number of infusion hours before discontinuing testing, with zero failures, was 7951 hours.</td><td>Pass</td></tr>
</table>

- Electrical, hardware, and mechanical safety testing per AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Electromagnetic compatibility testing per 60601-1-2:2007. In addition, testing for immunity to proximity fields from RF wireless communications equipment was conducted.
- Verification and validation of safety control mechanisms, alarms (per IEC 60601-1-8:2006), operating specifications (such as battery life), and environmental specifications
- Software verification and validation testing – Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.
- Human factors – Usability evaluation and human factors testing was conducted in accordance with IEC 62366-1:2015 and IEC 62366:2007 +A1:2014 as well as collateral standards of IEC 60601-1 with relevant human factors requirements.

The proposed device was tested to verify conformance with the design specifications and applicable industry standards. Validation and human factors evaluations for the VIC were conducted in simulated environments to ensure user needs and intended uses were met. A

clinical investigation was not conducted, as the bench testing and human factors testing is sufficient to show the product is substantially equivalent in performance for its intended use.

**Conclusion**

The performance data included in this premarket notification demonstrate that the proposed device is substantially equivalent to the predicate device.