November 10, 2022

Bard Access Systems
Nasreen Al-Quaid
Staff Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, UT

Re: K223198
Trade/Device Name: BD Intraosseous Vascular Access System EMS Powered Driver (D001003)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MHC
Dated: October 11, 2022
Received: October 13, 2022

Dear Nasreen Al-Quaid:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Joyce M. Whang -S

CAPT Alan Stevens
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223198

Device Name
BD Intraosseous Vascular Access System EMS Powered Driver (D001003)

Indications for Use *(Describe)*
The BD Intraosseous Vascular Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

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.

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Bard Access Systems, Inc. (Bard has joined BD)
Special 510(k) Premarket Notification
BD Intraosseous Vascular Access System EMS Powered Driver
510(k) Summary

510(k) Summary

21 CFR 807.92(a)

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

General Provisions	Submitter Name:	Bard Access Systems, Inc. (Bard has joined BD)
	Submitter Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Nasreen A. Al-Quaid Staff Regulatory Affairs Specialist
	Telephone Number:	484.569.2865
	Email:	Nasreenara.alquaid@bd.com
	Date of Preparation:	11/07/2022
Subject Device	Trade Name:	BD Intraosseous Vascular Access System EMS Powered Driver
	Common Name:	Intraosseous Infusion System
	Regulation Number:	21 CFR §880.5570
	Regulation Classification Name:	Hypodermic, Single Lumen Needle
	Regulatory Class:	II

Bard Access Systems, Inc. (Bard has joined BD)
Special 510(k) Premarket Notification
BD Intraosseous Vascular Access System EMS Powered Driver
510(k) Summary

	Product Code:	MHC
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	BD Intraosseous Infusion System
	Common Name:	Intraosseous Infusion System
	Regulation Number:	21 CFR §880.5570
	Regulation Classification Name:	Hypodermic, Single Lumen Needle
	Regulatory Class:	II
	Product Code:	MHC
	Classification Panel:	General Hospital
	510(k) Status:	K203193 (Concurrence date: March 4, 2021)
Device Description	The BD Intraosseous Vascular Access System provides clinicians and emergency personnel with access to the intraosseous space for resuscitation and lifesaving fluid delivery for up to 24 hours. The BD Intraosseous Vascular Access System consists of the following: •a single use hypodermic needle (with needle safety cap), •a powered or manual driver to assist with needle insertion, •an extension set, and •an adhesive-backed securement dressing. For insertions using the powered driver, the hypodermic needle includes a needle hub that mates with a stylet connected to a drive adapter hub. The drive adapter hub includes a ferromagnetic material that is attracted by the magnet in the powered driver and attaches to the powered driver prior to needle insertion. The BD Intraosseous Vascular Access System is an easy-grip, hand-held, battery-powered device used to assist in the insertion of the subject device needle through the bone cortex. The assembly of the hypodermic needle and stylet with connected drive adapter hub is referred to as the needle set.	

Bard Access Systems, Inc. (Bard has joined BD)
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BD Intraosseous Vascular Access System EMS Powered Driver
510(k) Summary

Intended Use	The BD Intraosseous Vascular Access System is intended to provide clinicians and emergency personnel with access to the intraosseous space.
Indications for Use	The BD Intraosseous Vascular Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.
Technological Characteristics	An Intraosseous Powered Driver is the technological principle for both the subject and predicate device. It is based on providing intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours. At a high level, the subject device, BD Intraosseous Vascular Access System EMS Powered Driver and the cited predicate device are based on the following same technological and use elements: • Intended Use, Indications for Use, Target Patient Population • Reusable Powered Intraosseous Driver- used to provide intraosseous access • Power Driver Attachment to Needle - at distal end of device and same insertion technique

Bard Access Systems, Inc. (Bard has joined BD)
Special 510(k) Premarket Notification
BD Intraosseous Vascular Access System EMS Powered Driver
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- Use of the same Needle Set Configurations – choice of use based on tissue depth
- Use of LED Battery Display – indication the status of the battery
- Use of an Operating Switch to run the device
- Use of a Motor and Circuit Board Assembly and Microcontroller ARM Processor
- Use of Lithium-ion Batteries to run the device

The modifications made to the predicate device include modifications to the design and technology, software and labeling. The following technological differences exist between the subject and predicate devices:

1. Design and Technology;
   - Change in driver shape, placement of LED battery indicator lights &operating switch.
   - Housing and Rear Cap material difference due to shape modification
   - Hardware and battery changes to facilitate replaceable battery
2. Software: Modification to structure of software (firmware).
3. Labeling: Separate IFU to support charging differences of the device

The following tables provides a summary comparison between the subject and predicate device.

Attribute	Subject Device BD Intraosseous Vascular Access System EMS Powered Driver	Predicate device BD Intraosseous Infusion System (K203193)	Discussion of Substantial Equivalence
Owner	Bard Access Systems, Inc.	Bard Access Systems, Inc.	Identical
510(k) status	Subject of this 510(k)	K203193	
Intended Use	The BD Intraosseous Vascular Access System is intended to provide clinicians	The BD Intraosseous Vascular Access System is intended to provide clinicians	Identical

Bard Access Systems, Inc. (Bard has joined BD)
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	and emergency personnel with access to the intraosseous space	and emergency personnel with access to the intraosseous space	
Indications for use	The BD Intraosseous Vascular Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.	The BD Intraosseous Vascular Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.	Identical
Powered Driver Use	Reusable	Reusable	Identical
Intended Patient Population	Adults and Pediatrics who require short-term (less than 30 days intraosseous infusion therapy	Adults and Pediatrics who require short-term (less than 30 days intraosseous infusion therapy	Identical

Bard Access Systems, Inc. (Bard has joined BD)
Special 510(k) Premarket Notification
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		General Device Description	The BD Intraosseous Vascular Access System provides clinicians and emergency personnel with access to the intraosseous space for resuscitation and lifesaving fluid delivery for up to 24 hours. The BD Intraosseous Vascular Access System consists of the following: •a single use hypodermic needle (with needle safety cap), •a powered or manual driver to assist with needle insertion, •an extension set, and •an adhesive-backed securement dressing. For insertions using the powered driver, the hypodermic needle includes a needle hub that mates with a stylet connected to a drive adapter hub. The drive adapter hub includes a magnetic insert that attaches to the powered driver prior to needle insertion. The BD Intraosseous Vascular Access System is an easy-grip, hand-held, battery-powered device used to assist in the insertion of the subject device needle through the bone cortex. The assembly of the hypodermic needle and stylet with connected drive adapter hub is referred to as the needle set.	The BD Intraosseous Vascular Access System provides clinicians and emergency personnel with access to the intraosseous space for resuscitation and lifesaving fluid delivery for up to 24 hours. The BD Intraosseous Vascular Access System consists of the following: •a single use hypodermic needle (with needle safety cap), •a powered or manual driver to assist with needle insertion, •an extension set, and •an adhesive-backed securement dressing. For insertions using the powered driver, the hypodermic needle includes a needle hub that mates with a stylet connected to a drive adapter hub. The drive adapter hub includes a magnetic insert that attaches to the powered driver prior to needle insertion. The BD Intraosseous Vascular Access System is an easy-grip, hand-held, battery-powered device used to assist in the insertion of the subject device needle through the bone cortex. The assembly of the hypodermic needle and stylet with connected drive adapter hub is referred to as the needle set.	Identical	

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Insertion Site	Adults: proximal tibia, distal tibia, and proximal humerus Pediatrics: proximal tibia, distal tibia proximal humerus, and the distal femur	Adults: proximal tibia, distal tibia, and proximal humerus Pediatrics: proximal tibia, distal tibia proximal humerus, and the distal femur	Identical
Needle Set Configurations	15mm (0-10 mm tissue depth) 25mm (0-20 mm tissue depth) 35mm (10-30 mm tissue depth) 45mm (20-40 mm tissue depth) 55mm (30-50 mm tissue depth)	15mm (0-10 mm tissue depth) 25mm (0-20 mm tissue depth) 35mm (10-30 mm tissue depth) 45mm (20-40 mm tissue depth) 55mm (30-50 mm tissue depth)	Identical
Powered Driver Attachment to Needle	Ferromagnetic material that is attracted by the magnet in the powered driver at the distal end of device	Ferromagnetic material that is attracted by the magnet in the powered driver at the distal end of device	Identical
Powered Driver Technique to Insert	Powered: Manually press needle set through soft tissue to bone. Check black depth marks. Drill needle set through bone until change in pressure is felt or to desired depth. Remove driver. Remove stylet. Connect IV extension set. Check placement. Monitor site.	Powered: Manually press needle set through soft tissue to bone. Check black depth marks. Drill needle set through bone until change in pressure is felt or to desired depth. Remove driver. Remove stylet. Connect IV extension set. Check placement. Monitor site.	Identical
Powered Driver Design - Shape	**In-Line Driver Shape**	Traditional Drill Shape	**Modification in Shape (Housing and Addition of Rear Threaded Cap). Changes to the housing shape do not raise new or different questions of safety or effectiveness.**
Powered Driver LED Battery Display	**Placement modification** of LED Battery Indicator light, indicating the status of the battery	LED Battery Indicator light, indicating the status of the battery	**Modification in Placement due to Shape**

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Powered Driver Design - Materials	Co-polyester **and 30% Glass-fiber reinforced polypropylene**	Copolyester	**Modification in Material (Housing and Rear Threaded Cap). Changes to the driver material are not patient contacting and do not raise new or different questions of safety or effectiveness.**
Power Driver Design -Switch	**Power Switch - Button**	Power Switch - Trigger	**Modification in Ergonomics of the Power Switch. Changes to the trigger location do not raise new or different questions of safety or effectiveness.**
Powered Driver Design - Internal Hardware	**Redesigned** Motor and Circuit board Assembly	Motor and Circuit board Assembly	**Redesigned to support battery type and shape change. Changes to the hardware do not raise new or different questions of safety or effectiveness.**
Powered Driver Battery Type	Lithium-ion Batteries **Primary, (Replaceable), Removable**	Lithium-ion Battery Secondary (Rechargeable), Non-Removeable	**Modification in Battery Type. Changes to the battery type do not raise new or different questions of safety or effectiveness.**
Powered Driver Software	**Updated** Firmware developed for 32-bit Microcontroller ARM processor	Firmware developed for 32-bit Microcontroller ARM processor	**Firmware was developed using the same architecture to support hardware changes. Changes to the firmware do not raise new or different questions of safety or effectiveness.**

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	Powered Driver Cleaning Method	Intermediate level disinfection	Intermediate level disinfection	Identical
	Powered Driver Service Life	1500 insertions at 10 seconds per insertion	1500 insertions at 10 seconds per insertion	Identical

A risk analysis was conducted in accordance with ISO *14971, Medical Devices – Risk Management for Medical Devices* to determine the impact of design & technology, software and labeling modifications to the device, the BD IO EMS Powered Driver. Attributes identified that presented different risks as per the risk analysis were mitigated using well-established methods and the following consensus standards for general use, listed below. Therefore, these differences in technological characteristics in the subject devices do not raise any significant changes in safety and effectiveness as compared to the predicate design.

Performance Tests

Applicable verification and validation tests have been performed in accordance with Design Controls as per 21 CFR §820.30. The following guidance documents and standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

Document Number	Revision	Title
ISO 14971	2019	Medical Devices – Risk Management for Medical Devices
ANSI AAMI ES 60601-1	2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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	IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances -Requirements and tests	
	IEC 60601-1-6	2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	
	IEC 60601-1-12	2020	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	
	IEC 60086-4	2019	Primary batteries - Part 4: Safety of lithium batteries.	
	UN3091	N/A	Lithium Battery Guidance Document	
	UN3090	N/A	Lithium Battery Guidance Document	
	UN38.3	N/A	UN Recommendations on the Transport of Dangerous Goods	
	AAMI TIR30	2011 (R2016)	Cleaning Reusable Medical Device	
	FDA Guidance	N/A	FDA Guidance Document, Reprocessing Medical Devices in Health Care Setting	
	FDA Guidance	2005	Applying Human Factors and Usability Engineering	
	IEC 62304	2015	Medical device software – Software life cycle processes	

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BD Intraosseous Vascular Access System EMS Powered Driver
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<tr><td>FDA Guidance</td><td>2005</td><td>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</td></tr>
<tr><td>FDA Guidance</td><td>2002</td><td>General Principles of Software Validation, Guidance for Industry and FDA Staff</td></tr>
<tr><td>FDA Guidance</td><td>2017</td><td>Deciding When to Submit a 510(k) for a Software Change to an Existing Device</td></tr>
<tr><td>ISO 11607-1</td><td>2019</td><td>Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems</td></tr>
<tr><td>ISTA 1G</td><td>2014</td><td>Packaged-Products Weighing 150 lb (68 Kg) Or Less (Random Vibration)</td></tr>
<tr><td>ISO 15223-1, 2</td><td>2016</td><td>Symbols to be Used with medical device labels</td></tr>
</table>

The subject device met all predetermined acceptance criteria derived from the above listed reference standards and demonstrated substantially equivalent performance as compared to the cited predicated device.
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<td>Summary of Substantial Equivalence</td>
<td>Based on the risk management activities, intended use, technological characteristics, and performance testing, the subject, BD IO EMS Powered Driver demonstrated to be substantial equivalent for its intended use and fundamental scientific technology as the cited predicate device.</td>
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