April 20, 2018

C.R. Bard, Inc
Mona Shahrebani
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K172511
Trade/Device Name: Hickman® TriFusion™ Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: March 23, 2018
Received: March 26, 2018

Dear Mona Shahrebani:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K172511

Device Name
Hickman® TriFusion™ Catheter

Indications for Use *(Describe)*

The Hickman® TriFusion™ Triple Lumen Long-Term Central Venous Catheter is indicated for use in attaining short term or long term vascular access for intravenous infusion therapy and blood sampling via the internal jugular vein, external jugular vein, and subclavian vein. All Hickman® TriFusion™ catheters are designed for apheresis, and the administration of I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal. The Hickman® TriFusion™ catheter incorporates three large, equal size lumens appropriate for apheresis procedures.

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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K172511

Hickman TriFusion Catheter

510(k) Summary

21 CFR 807.92

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:

Submitter Information:
Bard Access Systems, Inc. (BAS)
605 North 5600 West
Salt Lake City, Utah 84116

| | |
|---|---|
| Phone: | (801) 522-5967 |
| Fax: | (801) 522-4907 |
| Contact Person: | Mona Shahrebani, Regulatory Affairs Specialist |
| Date of Submission: | April 13, 2018 |
| Subject Device: | Hickman® TriFusion™ Catheter |
| Common or Usual Name: | Long-Term Intravascular Catheter |
| Classification Name: | Catheter, Intravascular, Therapeutic, Long-Term greater than 30 days |
| Regulatory Class: | Class II |
| Regulation Number: | 21 CFR 880.5970 |
| FDA Product Code: | LJS |

| | |
|---|---|
| Predicate Device: | Hickman® TriFusion™ Catheter |
| Common or Usual Name: | Long-Term Intravascular Catheter |
| Premarket Notification: | K041088 |
| Classification Name: | Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 days |
| Regulatory Class: | Class II |
| Regulation Number: | 21 CFR 880.5970 |
| FDA Product Code: | LJS |

**Device Description:**

The device description of the subject Hickman TriFusion Catheter is as follows:

- The Hickman® TriFusion™ Catheters are open-ended triple lumen radiopaque polyurethane catheters.
- The Hickman® TriFusion™ Catheters are 12 Fr triple lumen catheters with up to 27 cm insertion length.
- The Hickman® TriFusion™ Catheters have three equal sized lumens with the distal lumen extending beyond the proximal lumens.
- The proximal end of the Hickman® TriFusion™ Catheter consists of three Luer connectors, occlusion clamps, and priming volume ID tags.
- Catheters are provided sterile in two kit configurations, an Intermediate Tray and a Microintroducer (MI) Tray.

**Indications for Use of Device:**

The Hickman® TriFusion™ Triple Lumen Long-Term Central Venous Catheter is indicated for use in attaining short term or long term vascular access for intravenous infusion therapy and blood sampling via the internal jugular vein, external jugular vein, and subclavian vein. All Hickman® TriFusion™ catheters are designed for apheresis, and the administration of I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal. The Hickman® TriFusion™ catheter incorporates three large, equal size lumens appropriate for apheresis procedures.

**Technological Comparison to Predicate Devices:**

Technological characteristics of the subject Hickman® TriFusion™ Catheter are substantially equivalent with regard to the basic design and function of the predicate device, Hickman® TriFusion™ Catheter (K041088). The subject device differs in technological characteristics when compared to the predicate device in that the Luer connector of the subject devices are manufactured from a different material formulation of the base resin and colorant. These differences do not alter the intended use of the subject device and do not raise any new questions regarding safety or effectiveness when compared to the predicate device.

<table>
<tr><th colspan="3">Subject and Predicate Device Comparison Table</th></tr>
<tr><th></th><th>Subject Device- Hickman TriFusion Catheter</th><th>Predicate Device- Hickman TriFusion Catheter</th></tr>
<tr><td>Owner</td><td>Same as Predicate</td><td>Bard Access Systems, Inc.</td></tr>
<tr><td>Classification</td><td>Same as Predicate</td><td>LJS- 21 CFR 880.5970- Long-Term-Intravascular Catheter</td></tr>
<tr><td>510(k) Status</td><td>Subject of this Premarket Notification</td><td>K041088- Concurrence date November 01, 2004</td></tr>
<tr><td>Indications for Use</td><td>Same as Predicate</td><td>The Hickman® TriFusion™ Triple Lumen Long-Term Central Venous Catheter is indicated for use in attaining short term or long term vascular access for intravenous infusion therapy and blood sampling via the internal jugular vein, external jugular vein, and subclavian vein. All Hickman® TriFusion™ catheters are designed for apheresis, and the administration of I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal. The Hickman® TriFusion™ catheter incorporates three large, equal size lumens appropriate for apheresis procedures</td></tr>
<tr><td>Catheter Configurations</td><td>Same as predicate</td><td>
<table>
<tr><th></th><th>French Size</th><th>Length (Tip to Cuff)</th><th>Total Length</th></tr>
<tr><td rowspan="3">Insertion Length</td><td>12 Fr</td><td>19 cm</td><td>24 cm</td></tr>
<tr><td>12 Fr</td><td>23 cm</td><td>28 cm</td></tr>
<tr><td>12 Fr</td><td>27 cm</td><td>32 cm</td></tr>
</table>
</td></tr>
<tr><td>Catheter Material</td><td><u>Catheter Shaft</u><br>Same as predicate<br><u>Catheter Shaft Tip</u><br>Same as predicate<br><u>Trifurcation</u></td><td><u>Catheter Shaft</u><br>Polycarbonate Polyurethane<br><u>Catheter Shaft Tip</u><br>Polycarbonate Polyurethane<br><u>Trifurcation</u></td></tr>
</table>

<table>
<tr><th colspan="3">Subject and Predicate Device Comparison Table</th></tr>
<tr><th></th><th>Subject Device- Hickman TriFusion Catheter</th><th>Predicate Device- Hickman TriFusion Catheter</th></tr>
<tr><td></td><td>Same as predicate<br><u>Extension Legs</u><br>Same as predicate<br><u>Luer Connectors</u><br>Isoplast® 2510 Polyurethane with PolyOne Gray colorant</td><td>Polycarbonate Polyurethane<br><u>Extension Legs</u><br>Polyurethane<br><u>Luer Connectors</u><br>Isoplast®2530 Polyurethane with Americhem Gray colorant</td></tr>
<tr><td>Proximal Configuration</td><td>Luer Connectors – same as predicate<br>Priming Volume ID Tags – same as predicate<br>Occlusion Clamps – Small Size and Mini size<br><br>Note: An additional clamp (i.e., “Small Size”) was added as an option for the subject device with the only difference being a proportional dimension change. Please note the “small” size is larger than the “mini” size cleared with the predicate device.</td><td>Luer Connectors – three Luer connectors<br>Priming Volume ID Tags<br>Occlusion clamps – Mini size</td></tr>
<tr><td>Distal Configuration</td><td>Same as predicate.</td><td>Stepped atraumatic tip, a stepped-tip configuration with the distal lumen extending beyond the two proximal lumens. The proximal lumens terminate at the same distance from the trifurcation.</td></tr>
<tr><td>Gravity Flow Rates</td><td>Same as predicate</td><td><table><tr><th>Lumen with White Clamp</th><th>Lumen with Blue Clamp</th><th>Lumen with Red Clamp</th></tr><tr><td>115 ml/min</td><td>110 ml/min</td><td>114 ml/min</td></tr></table></td></tr>
</table>

**Performance Data:**

Verification tests were designed and performed in accordance with Design Controls as per 21 CFR §820.30. The following tests were conducted per guidance documents and standards in conjunction with in-house protocols to establish the performance of the device.

| **Verification Test** | **Standard Utilized** |
|---|---|
| Catheter Assembly Burst Strength | Bard internal standards and procedures |
| Catheter Assembly Tensile | ISO 10555-1: 2013, *Intravascular catheters -- Sterile and single-use catheters - Part 1: General Requirements* |
| Catheter Joint Durability Leak Test | |
| Luer Configuration: Luer Gauging | ISO 594-1: 1986, *Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment –Part 1: General Requirements*<br><br>ISO 594-2: 1998, *Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment- Part 2: Lock Fittings* |
| Luer Configuration: Liquid Leak | |
| Luer Configuration: Air Leak | |
| Luer Configuration: Unscrewing Torque | |
| Luer Configuration: Ease of Assembly | |
| Luer Configuration: Resistance to Overriding | |
| Luer Configuration: Stress Cracking | |
| Luer Configuration: Separation Force | |
| Cuff Tensile | ISO 10555-1: 2013, *Intravascular catheters -- Sterile and single-use catheters - Part 1: General Requirements* |
| Tip Tensile | |
| Gravity Flow | |
| Catheter Stiffness | FDA Guidance 1995, *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters* |
| Priming Volume | |
| Catheter Collapse | |
| Radiopacity | ASTM F640: 2012, *Standard test methods for determining radiopacity for medical use*<br><br>ISO 10555-1: 2013, *Intravascular catheters -- Sterile and single-use catheters - Part 1: General Requirements*<br><br>FDA Guidance 1995, *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters* |

Biocompatibility evaluation and testing was conducted in accordance with ISO10993-1, *Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.*

The following tests were performed per ISO 10993, *Biological evaluation of medical devices:*

| **Biocompatibility Test** | **Standard Utilized** |
|---|---|
| Cytotoxicity | ISO 10993-5:2009, *Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity* |
| Sensitization | ISO 10993-10:2010, *Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization* |
| Intracutaneous Reactivity | |
| Acute Systemic Toxicity | ISO 10993-11:2006, *Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity* |
| Material-Mediated Pyrogencitiy | |
| Subchronic Toxicity | ISO 10993-11:2006, *Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity*<br>ISO 10993-:2007, *Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation* |
| Genotoxicity | ISO 10993-3:2003, *Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity* |
| Implantation | ISO 10993-6:2007, *Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation* |
| Hemocompatibility | ISO 10993-4:(2002, amended 2006), *Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood* |

The subject Hickman TriFusion Catheter was adopted into the sterilization cycle per AAMI TIR28:2016, *Product adoption and process equivalence for ethylene oxide sterilization.* The sterilization cycle has been validated by half-cycle over-kill method in accordance with ANSI/AAMI/ISO 11135, *Sterilization of Healthcare Products.* Ethylene Oxide sterilization testing was conducted per ISO 10993-7:2008, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.* Additionally, LAL bacterial endotoxin testing was performed per ANSI/AAMI ST72*, Bacterial Endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing,* and USP<161> for bacterial endotoxin limits.

**Conclusions:**

Based on the indications for use, technological characteristics, and performance testing, the subject Hickman® TriFusion™ Catheter meets the requirements that are considered sufficient for its intended use and demonstrate substantial equivalence to the cited predicate device.