August 24, 2022

Bard Access Systems, Inc.
Teresa Do-Mccage
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K222232
Trade/Device Name: Sherlock 3CG® Tip Positioning System (TPS) Stylet/T-Lock Assembly
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: July 22, 2022
Received: July 25, 2022

Dear Teresa Do-Mccage:

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,

Payal Patel
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)*
K222232

Device Name
Sherlock 3CG® Tip Positioning System (TPS) Stylet/T-Lock Assembly

Indications for Use *(Describe)*
Catheter stylets provide internal reinforcement to aid in catheter placement. When used with the Sherlock 3CG® Tip Confirmation System (TCS), the Sherlock 3CG® TPS Stylet/T-Lock Assembly also provides the placer rapid feedback on catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection.

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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K222232 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:	Teresa Do-McCage Regulatory Affairs Specialist
	Telephone Number:	801.522.5959
	Email:	teresa.do-mccage@bd.com
	Date of Preparation:	8/24/2022
Subject Device	Trade Name:	Sherlock 3CG® Tip Positioning System (TPS) Stylet/T-Lock Assembly
	Common Name:	Long-Term Greater Than 30 Days Therapeutic Intravascular Catheter
	Regulation Number:	21 CFR §880.5970
	Regulation Classification Name:	Percutaneous, Implanted Long-Term Intravascular Catheter
	Regulatory Class:	II
	Product Code:	LJS
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	Sherlock 3CG® Tip Positioning System (TPS) Stylet/T-Lock Assembly
	Common Name:	Long-Term Greater Than 30 Days Therapeutic Intravascular Catheter
	Regulation Number:	21 CFR §880.5970

	Regulation Classification Name:	Percutaneous, Implanted Long-Term Intravascular Catheter
	Regulatory Class:	II
	Product Code:	LJS
	Classification Panel:	General Hospital
	510(k) Status:	K142267 (Concurrence date October 17, 2014)

Device Description	Bard Access Systems, Inc.'s Sherlock 3CG® Tip Positioning System (TPS) Stylet/T-Lock Assembly is a sterile, single use device 0.49 mm (0.019 in) outer diameter x 78.5 cm, made of specially-formulated materials designed to aid in the placement of specific Bard catheters, as well as any open ended, non-valved, polyurethane, peripherally inserted central catheters (PICCs) that meet the dimensional specifications of the stylet. The Sherlock 3CG® TPS Stylet/T-Lock Assembly is designed to work with catheters containing a minimum lumen diameter of 0.51mm (0.020 in). The stylet provides internal reinforcement to aid in catheter placement. The Sherlock 3CG® TPS Stylet/T-Lock Assembly may be used with the Sherlock 3CG® Tip Confirmation System (TCS) to provide catheter tip placement information during the procedure.
Intended Use	The Sherlock 3CG® TPS Stylet/T-Lock Assembly provides real time catheter tip location information through the use of passive magnet and cardiac electrical signal detection.
Indications for Use	Catheter stylets provide internal reinforcement to aid in catheter placement. When used with the Sherlock 3CG® Tip Confirmation System (TCS), the Sherlock 3CG® TPS Stylet/T-Lock Assembly also provides the placer rapid feedback on catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection.
Technological Characteristics	Technological characteristics of the subject Sherlock 3CG® Tip Positioning System (TPS) Stylet/T-Lock Assembly device are substantially equivalent to those of the cited predicate device with respect to intended use, indications for use, target patient population, operating principle, fundamental scientific technology, packaging configurations, sterility assurance level, and method of sterilization. The differences of the subject device from the predicate device are limited to the T-Lock Extension Set Assembly, a primary device component used in the subject/predicate device. The following tables provides a summary comparison between the subject and predicate device component (T-Lock Extension Set Assembly):

Attribute	Subject Device	Predicate device	Testing Conducted to Demonstrate Substantial Equivalence

	Owner	Bard Access Systems, Inc.	Same		
	510(k) status	Subject of this 510(k)	K142267		
	Device Configuration	Same	Sherlock 3CG® Procedure Kit • Sterile Components: Uncoated Tyvek® double pouch. • Non-sterile Components: Foil Pouch		
	Indications for use	Same	Catheter stylets provide internal reinforcement to aid in catheter placement. When used with the Sherlock 3CG® Tip Confirmation System (TCS), the Sherlock 3CG® TPS Stylet also provides the placer rapid feedback on catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection.		
	Duration of use	Same	Limited (<24 hours)		

	General Device Description	Same	Bard Access Systems, Inc.'s Sherlock 3CG® Tip Positioning System (TPS) Stylet is a sterile, single use device 0.49 mm (0.019 in) outer diameter x 78.5 cm, made of specially-formulated materials designed to aid in the placement of specific Bard catheters, as well as any open ended, non-valved, polyurethane, peripherally inserted central catheters (PICCs) that meet the dimensional specifications of the stylet. The Sherlock 3CG® TPS Stylet is designed to work with catheters containing a minimum lumen diameter of 0.51mm (0.020 in). The stylet provides internal reinforcement to aid in catheter placement. The Sherlock 3CG® TPS Stylet may be used with the Sherlock 3CG® Tip Confirmation System (TCS) to provide catheter tip placement information during the procedure.		
	Means of insertion	Same	Percutaneous		
	Insertion site	Same	Peripheral		
	Stylet Materials	Same	• Stainless steel core wire • Polyimide casing • Hydrophilic coating • Magnets (Neodymium-Iron-Boron) • Conductive epoxy • UV adhesive		
	T-Lock Connector Extension	**DESIGN** • Female Luer Lock Connector with wings	**DESIGN** • Female Luer Lock Connector without wings	Functional, Dimensional testing per ISO 594-2.	

	Set Assembly	• Septum captured in plastic cap • Cap removed from rotating collar	• Septum placed in shrink wrap ring • Cap provided on rotating collar	Particulate Matter testing per USP <788>.	
		MATERIAL	**MATERIAL**	Biocompatibility testing per ISO 10993-4, ISO 10993-5, ISO 10993-10, and ISO 10993-11.	
		• Female Luer Lock Connector: PVC with colorants	• Female Luer Lock Connector: Rigid PVC with colorant		
		• Slide Clamp – Polypropylene, white	• Slide Clamp – ABS, white		
		• T-Fitting (T-Connector) – MABS, clear	• T-Fitting (T-Connector) – PVC, clear		
		• Spin Lock (Rotating Collar) – MABS, clear	• Spin Lock (Rotating Collar) – Polycarbonate, clear		
		Same	Tubing: PVC		
		Same	Injection Stopple (Septum) – Polyisoprene		
	Stylet Pull Tab Material	Same	Polypropylene		
	Stylet Tether Material and Length	Same	• Medical grade Santoprene • TPV wire insulation • Copper tinsel wire • Tin coated brass crimp • 72 cm length		
	Stylet Connector Material	Same	• Acetal connector • Stainless Steel connector pin		
	Stylet Distal Tip Configuration	Same	Atraumatic tip		
	Magnetic Field	Same	Passive		

	Connection to sensor	Same	The Sherlock 3CG® TPS Sensor is connected to the Sherlock 3CG® TPS Stylet via the Sherlock 3CG® TPS Fin Assembly. This connection can be made through a sterile drape.		
	ECG Detectable	Same	Yes, the stylet serves as an intravascular ECG signal sensing wire.		
	Fin Assembly	Same	The fin assembly consists of two off-the-shelf pre-wired ECG electrodes that terminate within the "fin". The fin houses three corresponding stainless steel contacts, one each for applicable ECG lead and one for the Sherlock 3CG® Stylet, representing a 3-electrode ECG system.		
	ECG Electrodes	Same	The Sherlock 3CG® TPS System uses a 3-electrode ECG system for ECG signal detection. The three (3) leads consist of two (2) standard off-the-shelf body electrodes and one intravascular electrode (Sherlock 3CG® TPS Stylet). The three electrodes are connected to the ECG detection circuitry in the Sherlock 3CG® TPS Sensor through the Sherlock 3CG® Fin Assembly.		
	Tip Placement Location	Same	In the superior vena cava, near the cavoatrial junction.		
	Catheter Material	Same	Polyurethane		
	Catheter Sizes	Same	Specific Bard catheters, any open-ended, non-valved, polyurethane PICC catheter that meets the dimensional specifications of the stylet (0.020 inch minimum lumen diameter)		
	Stylet Dimensions	Same	0.019 inch outer diameter x 78.5 cm		

	Sterility	Same	Provided Sterile	

The technological differences listed above were evaluated using industry consensus standards, and as defined in the Risk Assessment. Therefore, these differences in technological characteristics between the subject and predicate devices do not raise new or different questions of safety or effectiveness.

Performance Tests

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

Test Description	Test Method
Clamp/ Flow rate Test	BD Internal Test Method
Leak /Pressure Test	BD Internal Test Method
Reseal Test	BD Internal Test Method
Stylet Removal Force	BD Internal Test Method
Joint Tensile	BD Internal Test Method
Gauging	ISO 594-2
Liquid Leakage	ISO 594-2
Air Leakage	ISO 594-2
Separation Force	ISO 594-2
Unscrewing Torque	ISO 594-2
Ease of Assembly	ISO 594-2
Resistance to Overriding	ISO 594-2
Stress Cracking	ISO 594-2
Particulate Testing	USP <788>

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.

Summary of Substantial Equivalence	Based on the risk management activities, intended use, technological characteristics, and performance testing, the subject Sherlock 3CG® TPS Stylet/T-Lock Assembly demonstrated to be substantial equivalent for its intended use and is as safe and as effective as the cited predicate device.