May 31, 2022

Bard Peripheral Vascular, Inc
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K221440
Trade/Device Name: Liverty™ TIPS Access Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 6, 2022
Received: May 24, 2022

Dear Prithul Bom:

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,

Misti Malone, PhD
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K221440

Device Name
Liverty TIPS Access Set

Indications for Use *(Describe)*
The BD Liverty TIPS Access Set is indicated for percutaneous transjugular liver access during diagnostic and interventional 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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Liverty™ TIPS Access Set

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:

Applicant:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, Arizona 85281
Phone:	(602) 830-5517
Fax:	(312) 949-0436
Contact Person:	Scott Johnson, Senior Regulatory Affairs Specialist
Date of Submission:	May 6, 2022

Subject Device:

Name of Device:	Liverty™ TIPS Access Set
Common or Usual Name:	Introducer, Catheter (Product Code: DYB)
Classification Panel:	Cardiovascular
Regulatory Class:	II
Regulation Number:	21 CFR 870.1340

Predicate Device:

Rösch-Uchida Transjugular Liver Access Set (K171820, cleared on March 9, 2018)

Reference Device:

Ring Transjugular Intrahepatic Access Set (K171820, cleared on March 9, 2018)

Device Description:

The BD Liverty™ TIPS Access Set consists of an introducer sheath, a steerable cannula, a needle, a 5F catheter, a 10F dilator, and a 12F dilator. This device is intended for percutaneous transjugular liver access during diagnostic and interventional procedures.

The curve at the distal end of the TipsStar™ steerable cannula can be adjusted by the operator *in-situ*, by turning the orange knob at the end of the cannula to achieve the optimal cannula curve angle. Before introduction of the needle into the cannula, the bright beige 5F catheter must be slid over the needle. This assembly is introduced as one unit through the cannula. The operator

then thrusts the needle / 5F catheter assembly through the liver parenchyma and into the portal vein to create the shunt. The introducer sheath is then advanced until it is positioned across the parenchymal tract. Following completion of diagnostic or interventional procedures, such as placement of a TIPS stent, the introducer sheath is removed.

Intended Use / Indications for Use:

The BD Liverty™ TIPS Access Set is indicated for percutaneous transjugular liver access during diagnostic and interventional procedures.

Technological Comparison to Predicate Device:

The Liverty™ TIPS Access Set has the following similarities to the predicate device, the Rösch-Uchida Transjugular Liver Access Set (K171820, cleared on March 9, 2018):

- Same intended use
- Same indications for use
- Same target patient population
- Same principle of operation
- Same fundamental scientific technology
- Same imaging capabilities
- Same sterility level and method of sterilization

All components of the subject device are of similar design and function as the components of the predicate device. The subject device has three additional features compared to the predicate device. Namely:

1. The stiffening cannula on the predicate device comes with a pre-set angle that must be manually adjusted *ex vivo* if the angulation is not appropriate for obtaining portal vein access. In contrast, the angulation of the TipsStar™ steerable cannula can be adjusted by the operator *in situ* throughout the procedure.
2. The predicate device uses a stylet to puncture through the liver parenchyma. To confirm portal vein access, the stylet must be removed. The needle in the subject device is hollow, which allows confirmation of portal vein access via blood withdrawal and contrast injection to be completed with the needle in place. This feature is leveraged from the design of the reference device, the Ring Transjugular Intrahepatic Access Set (K171820, cleared on March 9, 2018).

3. The subject device is provided with a removable puncture depth adapter attached to the 5F catheter hub. Unscrewing and separating the adapter from the 5F catheter hub increases the puncture depth of the needle / 5F catheter assembly by 1 cm. The predicate device does not have a similar depth adapter.

Each of these features are intended to improve procedural flow by minimizing the number of times access set components must be removed / replaced during a TIPS procedure.

Biocompatibility Testing:

Per ISO 10993-1 and FDA guidance, testing for physical and/or chemical characterization, cytotoxicity, sensitization, irritation/intracutaneous reactivity, material-mediated pyrogenicity, acute systemic toxicity, and hemocompatibilty (direct and indirect hemolysis, complement activation, uPTT, in vivo thrombogenicity) tests were performed on all device components of the subject device or on representative devices. All test results met the acceptance criteria, where applicable, or demonstrated that the device is biocompatible.

Performance Data:

To demonstrate substantial equivalence of the subject device, the Liverty™ TIPS Access Set, to the predicate device, both technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, tests for the following tests were performed:

- Introducer Sheath Inner Diameter
- Needle Assembly Length over Cannula
- Lie Distance
- Sheath Radiopacity
- Needle, 10F Dilator, 12F Dilator, 5F Catheter Radiopacity
- Needle Tip Ultrasound Visibility
- Device Surface Quality
- Needle Point
- Needle Assembly Flexible Portion Stiffness
- Needle Assembly Durability
- Cannula and Needle Corrosion Resistance
- Contrast Media Resistance
- Freedom from Leakage from Hemostasis Valve

- Freedom from Leakage from Sheath
- 5F Catheter Leakage
- Needle Assembly Air Leak
- Sheath Peak Tensile Force
- Sheath Torque Resistance
- Sheath Tracking Durability
- 10F Dilator, 12F Dilator, 5F Catheter Peak Tensile Force
- Needle Tube and Needle Hub Joint Strength
- Cannula Curve Angle
- Cannula Curve Durability
- Luer Performance
- Packaging Performance
- Human Factors Evaluation
- 10F Dilator Stiffness
- Introducer Sheath Kink Resistance
- Introducer Sheath Radial Strength
- Needle Assembly Penetration Force
- Radiopacity (Introducer Sheath)
- Needle Tip Ultrasound Visibility
- Simulated Use Testing

The results from these tests demonstrate that the technological characteristics and performance criteria of the Liverty™ TIPS Access Set are comparable to the predicate device and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Sterilization:

The Liverty™ TIPS Access Set is provided sterile. Sterilization validations were performed according to ISO 11135 and demonstrate that the sterilization chambers and cycle deliver a sterility assurance level (SAL) of 10^{-6} for the sterilization of the Liverty™TIPS Access Set.

Conclusions:

The subject device, the Liverty™ TIPS Access Set, and the predicate device share the same or similar characteristics: intended use, indications for use, target patient population, principle of operation, fundamental scientific technology, imaging capabilities, and sterility level and method

of sterilization. Additionally, the Liverty™ TIPS Access Set met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. Non-clinical testing demonstrated that the subject device, the Liverty™ TIPS Access Set, is as safe and effective as the legally marketed predicate device, the Rösch-Uchida Transjugular Liver Access Set. The available evidence demonstrates that the Liverty™ TIPS Access Set is substantially equivalent to Rösch-Uchida Transjugular Liver Access Set and does not raise new questions of safety or effectiveness.