August 1, 2024

Argon Medical Devices, Inc.
Jacquelyn Huyghue
Sr. Regulatory Affairs Specialist
1445 Flat Creek Road
Athens, Texas 75751

Re: K241145
Trade/Device Name: TLAB® Transvenous Liver Biopsy System (TF-18C)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 2, 2024
Received: July 2, 2024

Dear Jacquelyn Huyghue:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for

Colin K. Chen -S
Digitally signed by Colin K. Chen -S
Date: 2024.08.01 10:45:40 -04'00'

Jessica Carr
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241145

Device Name

TLAB® Transvenous Liver Biopsy System (TF-18C)

Indications for Use *(Describe)*

The TLAB® Transvenous Liver Biopsy System is intended to be used for percutaneous transjugular and transfemoral venous 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.

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510K Summary - K241145

Date Prepared:	July 31, 2024
Company:	Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, Texas 75751 USA Facility Registration number: 1625425
Contact:	Jacquelyn Huyghue Sr. Regulatory Affairs Specialist Phone: 412-568-3369 Fax: 903-677-9396 Email: jacquelyn.huyghue@argonmedical.com
Device Trade Name:	TLAB® Transvenous Liver Biopsy System
Device Common Name:	Catheter, Introducer
Device Classification Name:	Catheter, Introducer Class II Product code Product code DYB 21 CFR §870.1340 Review Panel: Cardiovascular Devices
Predicate Device(s):	Primary: K022634, TLAB® Transjugular Liver Access Set Reference: K213638, Traveler Portal Vein Access Set
Description of the Device:	The TLAB® Transvenous Liver Biopsy System is a single use, disposable, sterile device. The TLAB® Transvenous Liver Biopsy System consists of the following components: • 18-Gauge (18Ga) Flexcore Biopsy Needle • 7 French (7Fr) Introducer Sheath with a curved metal stiffener • 5 French (5Fr) Straight Catheter • 5 French (5Fr) Curved Catheter • Tissue Removal Swabs • Bending Tool (used for transfemoral access). The system is inserted percutaneously, introducing a guidewire into inferior vena cava (IVC) (from transfemoral venous access), or into the right hepatic vein (from transjugular access), using the 5 Fr curved catheter as wire introducing means. After removing the wire introducer, verification is performed to ensure that the protective sheath on the 7 Fr introducer is securely connected to avoid puncture. For transfemoral procedures, the bending tool in the kit is used to curve the metal stiffening cannula of 7Fr introducer. This curve should cause the caval wall to tent when the cannula is inserted into the intrahepatic region of the IVC. Next the 7 Fr introducer is inserted over the guidewire. Optionally, 5Fr Straight catheter is inserted coaxially into the 7Fr introducer to provide a smooth transition for 7Fr introducer over the guidewire. The guidewire and 5Fr straight catheter (if used) is then removed and the charged needle is inserted through the 7Fr introducer. The biopsy device is then discharged/fired to collect the specimen and is then removed from the patient. The specimen is expelled from the device onto a collection slide and/or placed into fixative for pathological evaluation using tissue removal swabs.

Indication for Use:	The TLAB® Transvenous Liver Biopsy System is intended to be used for percutaneous transjugular and transfemoral venous liver access during diagnostic and interventional procedures.

Technological Characteristics:	A comparison of the technological characteristics of the subject device and the predicate devices shows the TLAB® Transvenous Liver Biopsy System to be substantially equivalent to the current marketed predicate devices. Equivalence is established on in vitro performance testing, and similarities in indications for use, materials, packaging, technological characteristics, principle of operation, design features and sterilization process.

	Subject Device	**Primary Predicate**	**Reference Predicate**
	TLAB® Transvenous Liver Biopsy System	**TLAB® Transjugular Liver Biopsy System K022634**	**Traveler 0.038 Stylet Portal Vein Access (TPS001), Traveler 21ga Needle Portal Vein Access Set (TPS002), Traveler 16ga Needle Portal Vein Access Set (TPS003) K213638 for Bending Tool Only**
Manufacturer	Argon Medical Devices, Inc.	Argon Medical Devices, Inc.	Argon Medical Devices, Inc.
FDA Clearance	K241145	K022634	K213638
Class	II	**Same**	**Same**
Device Classification Name	Catheter introducer	**Same**	**Same**
Regulation	21 CFR §870.1340	**Same**	**Same**
Product Code	DYB	**Same**	**Same**
Clinical Comparison			
Intended Use	Intended for use in obtaining liver histology samples via transjugular and transfemoral venous approaches.	**Same – intended to collect liver samples** The TLAB® Transjugular Liver Biopsy Instrument is designed to perform consistently in typical and tortuous anatomy to collect quality liver samples.	The Traveler™ Portal Vein Access Set is intended for transjugular liver access in diagnostic and interventional procedures.

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Principle of Operation	The patient is prepared for transfemoral or transjugular access per facility clinical protocols. The components are removed from the Transvenous Liver Biopsy System package using sterile technique. The components are then flushed with heparinized saline or similar isotonic solution before use. Prior to obtaining femoral or jugular access, the needle is charged by pulling back on the plunger until a firm click is felt and heard. The device is then placed on the table in the sterile environment. After prepping the device, the user will obtain femoral or jugular access. They will introduce and seat a guidewire into the right femoral vein using a wire introducing means, such as a 5 Fr curved catheter or by other methods. After removing the wire introducing means, the user will confirm that the protective sheath on the 7 Fr introducer is securely connected to avoid puncture and insert the 7 Fr introducer over the guidewire. The Bending Tool is used to increase the bend on the metal 7F Introducer with protective sheath per the anatomy of the patient The user will make any appropriate adjustments to avoid capsular perforation	**Same – Subject device includes additional access point** Establish jugular access and maintain access with .035" guidewire, Use the MPA catheter to guide guidewire into right hepatic vein. Remove MPA catheter. Introduce 7F introducer sheath over the guidewire and into the right hepatic vein. Remove guidewire. Lock needle by pulling back on the plunger until a click is heard. Introduce the needle through the safety guide until the black mark meets the beginning of the funnel. Advance the needle. Hold the introducer system in place & remove the needle. Pull back on the plunger until a click is heard, then push plunger forward to expose the specimen. Remove sample by rolling it out of the notch with a swab. Place sample in formalin. Re-insert biopsy needle and repeat.	The Traveler Portal Vein Access Set is used to deliver an endoprosthetic shunt through the liver parenchyma. This is accomplished by using the Portal Vein Access Set to gain access to the hepatic vein and guide a sharp puncture tool toward the parenchyma. The puncture tool is used to make a pathway from the hepatic vein to the portal vein, then the pathway is dilated to provide access for a larger sheath. The shunt (not included) is inserted through the sheath and deployed through the pathway. All of the Portal Vein Access Set components are then removed.

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	using clinical judgment. Once the device is inserted, the user may inject contrast material through the side port in the valve assembly of the 7 Fr Introducer. After confirming that the desired location has been achieved, then the user will remove the guidewire and insert the charged needle through the catheter system. The biopsy device is then discharged/fired to collect the specimen and is then removed from the patient. The specimen is expelled removed from the device onto a collection slide and/or placed into fixative for pathological evaluation. If additional samples are needed, the biopsy device is re-charged, reinserted into patient, discharged/fired to collect specimen, and removed from patient. When the collection of samples is finished and if used, the system is removed from the patient and disposed. Once the patient has been prepped, and hepatic pressure measurements have been taken, the procedure can vary in length from five to ten minutes.		
Mechanism of Action	Mechanical	**Same**	**Same**

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Indication for Use	The TLAB® Transvenous Liver Biopsy System is intended to be used for percutaneous transjugular and transfemoral venous liver access during diagnostic and interventional procedures.	**Similar** This device is intended to be used for percutaneous transjugular liver access during diagnostic and interventional procedures.	The Portal Vein Access Set is intended for transjugular liver access during diagnostic and interventional procedures.
Contraindication	None Known. Sound professional judgement should be used to determine if use of this product is inadvisable due to specific patient characteristics, including, but not limited to occluded IVC, occluded femoral vein, occluded internal jugular vein and possibly a short length of the intrahepatic IVC.	None Known. Sound professional judgment should be used to determine if use of this product is inadvisable due to specific patient characteristics, including, but not limited to: thrombosis of the internal jugular vein, untreated infections or reaction to contrast medium.	None Known
Target Patient Population	Adult patients to include elderly adults, any gender, race, or ethnicity.	Not Specified	Any patient that requires a transjugular intrahepatic portosystemic shunt (TIPS) endoprosthesis also requires that a clinician use a TIPS delivery system to place the endoprosthesis within the liver parenchyma. Patients that require a TIPS endoprosthesis commonly have a general liver disease such as cirrhosis or hepatitis B or C, and the disease progression resulted in narrowed or occluded blood vessels within the liver. In turn, the narrowed or occluded vessels increase the patient's blood pressure in the hepato-portal system, and a TIPS endoprosthesis is placed to

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			reduce the patient's blood pressure within that system. Patients can be any gender or age, but they are more commonly 40 years old or older.
Single Use	Yes	**Same**	**Same**
Supplied Sterile	Yes	**Same**	**Same**
Device Description	The TLAB® Transvenous Liver Biopsy System is intended to be used for percutaneous transjugular and transfemoral venous liver access during diagnostic and interventional procedures. The device is a single use, disposable sterile device. The TLAB® Transvenous Liver Biopsy System consists of the following components: • 18-Gauge (18G) Flexcore Biopsy Needle, 65 cm overall length, 17mm notch, 20.83 maximum throw • 7 French (7F) Introducer with Protective Sheath and Valve Assembly with Safety Guide, 60 cm overall length and a curved metal stiffener • 5 French (5F) Curved Catheter, 80 cm overall length	**Similar – difference is bending tool used in Subject device for femoral access** This device is intended to be used for percutaneous transjugular liver access during diagnostic and interventional procedures. The device is a single use, disposable sterile device. Each TLAB® System contains: • Flexcore® Biopsy Needle, 18 ga or 19 ga, 65 cm overall length, 17 mm notch, 20 mm throw • 7 Fr Introducer with Protective Sheath and Valve Assembly with Safety Guide, 60 cm overall length and a curved metal stiffener • 5 French (5F) Straight Catheter • 5 French (5F) Curved Catheter • Tissue Removal Swabs, 10 cm length, polyurethane foam tip, nylon handle • 5 Fr Curved Catheter, 80 cm overall length • 5 Fr Straight Catheter, 65 cm overall length for smoother transition between the 7 fr	Each Portal Vein Access Set contains a 10F wall-reinforced Introducer Sheath with radiopaque tip, a 10F Dilator, a 5F MPA catheter, tool that comes in the following variations: 0.038" Stylet with a 5Fr Stylet Catheter (separated with a removable spacer clip), a 21ga Needle/5Fr Catheter or 16ga Needle/7Fr Catheter (both are separated with a removable spacer clip) and a bending tool. The 14ga stiffening cannula with cannula sheath and the 16ga needle have a curved end, with a directional handle that indicates the direction of the curve. The 10F Introducer OnlySheath hemostatic valve is designed to allow entry of a 13F (4.3mm/0.171") access sleeve but taper down to a 10F inner diameter. a puncturing tool

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	• 5 French (5F) Straight Catheter,65 cm overall length for smoother transition between the 7 fr Introducer and guide wire • Tissue Removal Swabs 10cm length, polyurethane foam tip, nylon handle • Bending Tool (for transfemoral access)	Introducer and guide wire	
Technical Design and Biological Comparison			
Flexcore Biopsy Needle			
Guage Size	18ga	18 ga or 19 ga	N/A
Overall Length	65cm	**Same**	N/A
Notch Size	17mm	**Same**	N/A
Throw Length	20mm	**Same**	N/A
Tip Geometry	Bevel	**Same**	N/A
Composition	Flex Sheath: PEEK Cannula: 304 Stainless Steel Stylet: 304 Stainless Steel	**Same**	N/A
Introducer Sheath			
Introducer size	7F includes metal stiffener with Protective Sheath and Valve Assembly with Safety Guide	**Same**	N/A
Overall Length (cm)	60 cm	**Same**	N/A
Composition	• Sheath hub: HDPE • Sheath tip: HDPE	**Same**	N/A

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	• 7F Introducer Stiffening Cannula: 304 Stainless Steel • Torque Handle Orientation Tab: Polycarbonate • Needle Guide (Safety Funnel): Polycarbonate		
Curved Catheter			
Size	5F	**Same**	N/A
Overall Length (cm)	80cm	**Same**	N/A
Composition	• Catheter Hub: Polycarbonate • Catheter Shaft (braided): Nylon, barium sulfate, stainless steel • Catheter Tip: Pebax, bismuth subcarbonate, titanium dioxide	**Same**	N/A
Straight Catheter			
Size	5F	**Same**	N/A
Overall Length (cm)	65cm	**Same**	N/A
Composition	• Catheter Hub: Polycarbonate • Catheter Shaft Nylon, barium sulfate • Catheter Tip: Pebax, bismuth subcarbonate, titanium dioxide	**Same**	N/A
Tissue Removal Swabs			
Length (cm)	10 cm length	**Same**	N/A
Composition	• Tip: polyurethane foam • Handle: Nylon	**Same**	N/A

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Bending Tool			
Length (inches)	4 inches	N/A	4 inches
Composition	302 Stainless Steel	N/A	302 Stainless Steel
Performance Testing	Dimensional Visual Radiopacity Corrosion Resistance Simulated Use Tensile Strength Torque Strength Liquid Leakage Luer Functional Testing – ISO 80369-7 Catheter Functional Testing – ISO 10555-1 Resistance to Breakage - ISO 9626 Shipping Qualification	**Similar - with testing performed to current standards on Subject Device** Dimensional Visual Radiopacity Corrosion Resistance Simulated Use Tensile Strength Torque Strength Liquid Leakage Luer Functional Testing 594-1, -2 Catheter Functional Testing – ISO 10555-1 Shipping Qualification	Radiopacity Echogenicity Corrosion Resistance Dimensional & Functional Fit Tensile Strength Torque Strength Test Liquid Leakage Air Leakage Burst Pressure Flow Rate Simulative Use - performance testing including dimensional, surface and compatibility of components Luer Functional Testing Shipping Test
Non-Clinical, Animal Study	No	Yes	No
Clinical Study	No	yes	No
Biocompatible	Yes, Direct circulating blood / Limited (<24 hours)	**Same**	Yes, Direct circulating blood / Limited (<24 hours)
Non-pyrogenic	Yes	**Same**	Yes

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Biological Comparison	• Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-23) • Irritation or Intracutaneous Reactivity (ISO 10993-10) • Material Mediated Pyrogen (ISO 10993-11) • Acute Systemic Toxicity (ISO 10993-11 • Hemocompatibility (ISO10993-4) ○ In-vitro Blood Assay ○ Complement Activation, SC5b-9 ○ Heparinized Platelet and Leucocyte Counts ○ Partial Thromboplastin Time (PTT) ○ ASTM Hemolysis Assay, Direct and Extract Methods (ISO)	• Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-23) • Irritation or Intracutaneous Reactivity (ISO 10993-10) • Material Mediated Pyrogen (ISO 10993-11) • Acute Systemic Toxicity (ISO 10993-11 • Hemocompatibility (ISO10993-4) o In-vitro Blood Assay o Complement Activation, SC5b-9 o Heparinized Platelet and Leucocyte Counts o Partial Thromboplastin Time (PTT) o ASTM Hemolysis Assay, Direct and Extract Methods (ISO)	Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-10) • Intracutaneous Irritation (ISO 10993-10) • Acute Systemic Toxicity (ISO 10993-11) • Material Mediated Pyrogen (ISO 10993-11) • Hemocompatibility (ISO10993-4) o ASTM Hemolysis – Direct and Indirect Contact o Complement Activation, SC5b-9 o In Vivo Thrombogenicity Platelet and Leucocyte Counts o Partial Thromboplastin Time (PTT)
Packaging Configuration	Sterile Barrier Packaging Materials: The 6 system components are sealed individually in Tyvek/poly 1073B pouches. The individual pouches are inserted into a master Tyvek/poly 1073B pouch and labeled. 5 master system pouches are placed in a shipper box and labeled. 4 shippers are packaged into a corrugated cardboard box for sterilization.	**Similar – same configuration without the bending tool** The 5 system components are sealed individually in Tyvek/poly 1073B pouches. The individual pouches are inserted into a master Tyvek/poly 1073B pouch and labeled. 5 master system pouches are placed in a shipper box and labeled. 4 shippers are packaged into a corrugated cardboard box for sterilization.	The components of each kit are packaged in a PETG Tray and inserted into a labeled poly/Tyvek pouch. The labeled pouch is placed into a labeled shelf carton with one (1) IFU.

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Sterilization	Minimum SAL 10^{-6}, EtO	Same	Minimum SAL 10-6, EtO
Shelf-Life	3 years	Same	3 years

Non-Clinical Data (Bench-top Testing):

No performance standards have been established under section 514, performance standards, of the Food, Drug and Cosmetic Act for these devices.

A series of testing was conducted in accordance with protocols based on requirements outlined in guidance and industry standards and the below were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

The following tests were performed under the specified testing parameters to support the TLAB® Transvenous Liver Biopsy System substantial equivalence:

- Dimensional
- Visual
- Radiopacity
- Corrosion Resistance
- Simulated Use
- Tensile Strength
- Torque Strength
- Liquid Leakage
- Luer Functional Testing – ISO 80369-7
- Catheter Functional Testing – ISO 10555-1
- Resistance to Breakage - ISO 9626
- Shipping Qualification Testing
- Design Validation
- Summative Usability

Non-Clinical Data Biocompatibility

Biocompatibility is established for the TLAB® Transvenous Liver Biopsy System according to ISO 10993-1:2020 as an external communicating, circulating blood with limited duration <24hrs.

All studies were performed following the approved protocol under Good Laboratory Practices (GLP) in compliance to FDA GLP, 21 CFR Part 58.

The following Biocompatibility Testing was previously performed under the Predicate device and is applicable to the TLAB® Transvenous Liver Biopsy System:

- ISO10993-5 Cytotoxicity
- ISO10993-10 Sensitization
- ISO10993-23 Irritation or Intracutaneous Reactivity
- ISO10993-11 Material Mediated Pyrogen
- ISO10993-11 Acute Systemic Toxicity
- ISO 10993-4 Hemocompatibility –
    - ASTM Hemolysis Assay, Direct and Extract Methods (ISO)
    - In Vivo Thrombogenicity Study (ISO)

The following testing was selected and performed anew based on ISO 10993-1:2018 and FDA Guidance are as follows (Flexible SABD 18GA, 7F Introducer, 5F Straight Catheter, and 5F MPA Catheter):

- ISO10993-4 Hemocompatibility
    - Complement Activation Assay, SC5b-9 Method with Comparison Article (ISO)
    - Partial Thromboplastin Time (PTT) Assay with Comparison Article (ISO)
    - Heparinized Platelet and Leukocyte Count Assay with Comparison Article (ISO)

Conclusion:

The TLAB® Transvenous Liver Biopsy System introduces no additional clinical risk based upon the performance of a literature search, its comparable intended use and mechanism of action.

Based on performance testing in-vitro, similar indications for use, materials, technological characteristics, principle of operation, design features and sterilization process, the TLAB® Transvenous Liver Biopsy System is substantially equivalent to the predicate device..
