June 2, 2026

Zhejiang Kindly Medical Device Co., Ltd.
% Evan Hu
Technical and Regulatory Director
Shanghai Mind-Link Consulting Co., Ltd.
377 Tianzhu Rd., Jiading
Shanghai, 201801
China

Re: K252899
Trade/Device Name: Female Culture Device; Male Culture Device; Transfer Device; Access Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: April 30, 2026
Received: April 30, 2026

Dear Evan Hu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

DAVID WOLLOSCHECK -S

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252899

Device Name
Female Culture Device; Male Culture Device; Transfer Device; Access Device

Indications for Use *(Describe)*
Female Culture Device is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a male Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

Male Culture Device is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a female Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

Transfer Device is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a male Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

Access Device is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a female Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

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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K252899 - 510(k) Summary

1. **Preparation date: June 2, 2026**

2. **Submitter**

Manufacturer: Zhejiang Kindly Medical Device Co., Ltd.
Address: No.758, 5th Binhai Road Binhai Industrial Park, Longwan District, WENZHOU Zhejiang, CN 325025
Contact person: ZHANG Qian, 86 13858871856, zhangqian@kdlchina.com
Submission correspondent: Evan Hu, 86-18616124827, evan.ww.hu@outlook.com

3. **Device**

Trade/Device Name: Female Culture Device; Male Culture Device; Transfer Device; Access Device
Regulation Number: 21 CFR 862.1675
Common Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
Regulatory Class: II
Product Code: JKA
Review Panel: Clinical Chemistry

4. **Predicate device**

510(k) number: K222478
Trade name: BD Vacutainer® Luer-Lok™ Access Device, BD Vacutainer® Blood Transfer Device
Regulation Number: 21 CFR 862.1675
Common Name: Tubes, Vials, Systems, Serum Separators, Blood Collection
Regulatory Class: II
Product Code: JKA
Review Panel: Clinical Chemistry

5. **Device description**

The Female Culture Device, Male Culture Device, Transfer Device, and Access Device are four sterile, single-use medical instruments designed for collecting blood from a catheter hub or Luer connector. Each device is used in conjunction with a vacuum-assisted collection container, such as a blood collection tube or sampling bottle, to draw blood from an intravenous (IV) catheter. The devices are all constructed from a SUS304 stainless steel needle, an ABS adapter hub, a PP holder, a PP/PE luer lock cap and a synthetic rubber sleeve. Optional accessories may include a Luer lock cap, or a holder insert to accommodate various collection container sizes. These devices are intended for use by trained healthcare professionals only. The primary distinctions among these models lie in their physical structure and dimensions. Each

device is compatible with collection sets that feature either a male or female Luer connector, allowing for the collection of blood cultures.

To maintain a 5-year shelf life, the devices are sterilized with EO gas and packaged in a Tyvek® pouches.

Table 1 Device specifications

Device	Needle Gauge	Needle Length	Holder length	Luer Adapter Hub Color
Female culture device	20G, 21G	19mm, 17.5mm	61.8mm	Transparent
Male culture device			61.7mm	Blue, Transparent
Transfer device			63.5mm	Transparent
Access device			63mm	Blue, Transparent

6. Indications for use/Intended use

Female Culture Device is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a male Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

Male Culture Device is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a female Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

Transfer Device is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a male Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

Access Device is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a female Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.

7. Comparison of technological characteristics between proposed and predicate devices

Table 2 Technical characteristics substantial equivalence comparison table- **Female Culture Device**.

Characteristics	**Proposed device** **Female Culture Device**	**Predicate device** **K222478** **BD Vacutainer® Blood Transfer Device**	**Comments**
Indications for Use/Intended Use	**Female Culture Device** is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a male Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.	The **BD Vacutainer® Blood Transfer Device** is a sterile, single use, noninvasive medical device intended to be used by healthcare professionals for the safe, closed-system, needleless transfer of venous blood from a BD Luer-Lok™ tip syringe into evacuated blood collection tube(s) or blood culture bottle(s) for in vitro diagnostic testing.	Same: same fundamental meaning or core principles.
Product Code	JKA	JKA	Same
Class	II	II	Same
Number of Uses	Single use	Single use	Same
Structure and material	Hub (ABS) Non-patient (NP) needle tube (SUS 304) Needle sleeve (Isoprene Rubber) Holder (PP) Wider holder (PP) Luer lock cap (PP and/or PE)	Hub (Polycarbonate) Non-patient (NP) Cannula (Stainless Steel) Rubber Sleeve (Isoprene Rubber) Holder (Polypropylene (PP))	#1
Device size/length	61.8mm	61.98 mm (2.44 in),	#2
Non-patient cannula size	20G, 21G	20G	#3
Luer connector	Compliant with ISO 80369-7 Standard Female Luer	Compliant with ISO 594 Standard Female Luer	Same: ISO 80369-7 is an updated version of ISO 594

Characteristics	Proposed device Female Culture Device	Predicate device K222478 BD Vacutainer® Blood Transfer Device	Comments
Method of collection or operation	Attache the device's female Luer connector to a male luer port of the syringe or catheter set. Transfer the specimen into the collection tube or sampling bottle.	Attache the device's female Luer connector to a male luer port of the syringe or catheter set. Transfer the specimen into the collection tube or sampling bottle.	Same
Sample collected	Blood, Blood culture	Blood, Blood culture	Same
Biocompatibility	ISO 10993 Compliant including: • Cytotoxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility • Material mediated pyrogenicity	ISO 10993 Compliant including: • Cytotoxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility • Material mediated pyrogenicity	Same
Sterilization Method	EO with SAL 10^{-6}	EO with SAL 10^{-6}	Same

Table 3 Technical characteristics substantial equivalence comparison table- **Male Culture Device**.

Characteristics	Proposed device Male Culture Device	Predicate device K222478 BD Vacutainer® Luer-Lok™ Access Device	Comments
Indications for Use/Intended Use	**Male Culture Device** is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a female Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.	The **BD Vacutainer® Luer-Lok™ Access Device** is a sterile, single use, noninvasive device intended to be used by healthcare professionals for safe, closed-system venous blood collection from a female Luer of a catheter port or blood collection set, directly into an evacuated blood collection tube(s) for in vitro diagnostic testing. This device may also be used with a blood collection set with a female Luer to collect blood cultures.	Same: same fundamental meaning or core principles.
Product Code	JKA	JKA	Same
Class	II	II	Same
Number of Uses	Single use	Single use	Same
Structure and material	Hub (ABS) Non-patient (NP) needle tube (SUS 304) Needle sleeve (Isoprene Rubber) Holder (PP) Wider holder (PP) Luer lock cap (PP and/or PE)	Hub (Polycarbonate) Non-patient (NP) Cannula (Stainless Steel) Rubber Sleeve (Isoprene Rubber) Holder (Polypropylene (PP))	#1

Characteristics	Proposed device Male Culture Device	Predicate device K222478 BD Vacutainer® Luer-Lok™ Access Device	Comments
Device size/length	61.7mm	63.42 mm (2.50 in)	#2
Non-patient cannula size	20G, 21G	20G	#3
Luer connector	Compliant with ISO 80369-7 Standard Male Luer	Compliant with ISO 594 Standard Male Luer	Same: ISO 80369-7 is an updated version of ISO 594
Method of collection or operation	- Intravenous catheter blood collection from a female Luer port: Attach the device's male Luer connector to the female Luer port of the IV catheter. Transfer the specimen into the collection tube or sampling bottle. - Blood collection from a blood collection set (using wingset with a female Luer): Attach the device's male Luer connector to the female Luer connector of the winged infusion/collection set. Following standard venipuncture protocol, transfer the blood specimen from the patient into the collection tube or sampling bottle.	- Intravenous catheter blood collection from a female Luer port: Attach the device's male Luer connector to the female Luer port of the IV catheter. Transfer the specimen into the collection tube or sampling bottle. - Blood collection from a blood collection set (using wingset with a female Luer): Attach the device's male Luer connector to the female Luer connector of the winged infusion/collection set. Following standard venipuncture protocol, transfer the blood specimen from the patient into the collection tube or sampling bottle.	Same
Sample collected	Blood, Blood culture	Blood, Blood culture	Same
Biocompatibility	ISO 10993 Compliant including: • Cytotoxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility • Material mediated pyrogenicity	ISO 10993 Compliant including: • Cytotoxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility • Material mediated pyrogenicity	Same
Sterilization Method	EO with SAL 10^{-6}	EO with SAL 10^{-6}	Same

Table 4 Technical characteristics substantial equivalence comparison table- **Transfer Device**.

Characteristics	**Proposed device** **Transfer Device**	**Predicate device** **K222478** **BD Vacutainer® Blood Transfer Device**	**Comments**
Indications for Use/Intended Use	**Transfer Device** is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a male Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.	The **BD Vacutainer® Blood Transfer Device** is a sterile, single use, noninvasive medical device intended to be used by healthcare professionals for the safe, closed-system, needleless transfer of venous blood from a BD Luer-Lok™ tip syringe into evacuated blood collection tube(s) or blood culture bottle(s) for in vitro diagnostic testing.	Same: same fundamental meaning or core principles.
Product Code	JKA	JKA	Same
Class	II	II	Same
Number of Uses	Single use	Single use	Same
Structure and material	Hub (ABS) Non-patient (NP) needle tube (SUS 304) Needle sleeve (Isoprene Rubber) Holder (PP) Luer lock cap (PP and/or PE)	Hub (Polycarbonate) Non-patient (NP) Cannula (Stainless Steel) Rubber Sleeve (Isoprene Rubber) Holder (Polypropylene (PP))	#1
Device size/length	63.5mm	61.98 mm (2.44 in),	#2
Non-patient cannula size	20G, 21G	20G	#3
Luer connector	Compliant with ISO 80369-7 Standard Female Luer	Compliant with ISO 594 Standard Female Luer	Same, ISO 80369-7 is an updated version of ISO 594
Method of collection or operation	Attach the device's female Luer connector to a male luer port of the syringe or catheter set. Transfer the specimen into the collection tube or sampling bottle.	Attach the device's female Luer connector to a male luer port of the syringe or catheter set. Transfer the specimen into the collection tube or sampling bottle.	Same
Sample collected	Blood, Blood culture	Blood, Blood culture	Same
Biocompatibility	ISO 10993 Compliant including: • Cytotoxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility	ISO 10993 Compliant including: • Cytotoxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility	Same

Characteristics	Proposed device Transfer Device	Predicate device K222478 BD Vacutainer® Blood Transfer Device	Comments
	• Material mediated pyrogenicity	• Material mediated pyrogenicity	
Sterilization Method	EO with SAL 10^{-6}	EO with SAL 10^{-6}	Same

Table 5 Technical characteristics substantial equivalence comparison table- **Access Device**.

Characteristics	Proposed device Access Device	Predicate device K222478 BD Vacutainer® Luer-Lok™ Access Device	Comments
Indications for Use/Intended Use	**Access Device** is used for the collection of blood from a catheter hub or luer connector via vacuum-assisted collection device such as vacuum blood collection tube, sampling bottle. This device may also be used with a collection set with a female Luer to collect blood cultures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.	The **BD Vacutainer® Luer-Lok™ Access Device** is a sterile, single use, noninvasive device intended to be used by healthcare professionals for safe, closed-system venous blood collection from a female Luer of a catheter port or blood collection set, directly into an evacuated blood collection tube(s) for in vitro diagnostic testing. This device may also be used with a blood collection set with a female Luer to collect blood cultures.	Same: same fundamental meaning or core principles.
Product Code	JKA	JKA	Same
Class	II	II	Same
Number of Uses	Single use	Single use	Same
Structure and material	Hub (ABS) Non-patient (NP) needle tube (SUS 304) Needle sleeve (Isoprene Rubber) Holder (PP) Luer lock cap (PP and/or PE)	Hub (Polycarbonate) Non-patient (NP) Cannula (Stainless Steel) Rubber Sleeve (Isoprene Rubber) Holder (Polypropylene (PP))	#1
Device size/length	63mm	63.42 mm (2.50 in)	#2
Non-patient cannula size	20G, 21G	20G	#3
Luer connector	Compliant with ISO 80369-7 Standard Male Luer	Compliant with ISO 594 Standard Male Luer	Same, ISO 80369-7 is an updated version of ISO 594
Method of collection or operation	- Intravenous catheter blood collection from a female Luer port: Attach the device's male	- Intravenous catheter blood collection from a female Luer port: Attach the device's male	Same

Characteristics	Proposed device Access Device	Predicate device K222478 BD Vacutainer® Luer-Lok™ Access Device	Comments
	Luer connector to the female Luer port of the IV catheter. Transfer the specimen into the collection tube or sampling bottle. - Blood collection from a blood collection set (using wingset with a female Luer): Attach the device's male Luer connector to the female Luer connector of the winged infusion/collection set. Following standard venipuncture protocol, transfer the blood specimen from the patient into the collection tube or sampling bottle.	Luer connector to the female Luer port of the IV catheter. Transfer the specimen into the collection tube or sampling bottle. - Blood collection from a blood collection set (using wingset with a female Luer): Attach the device's male Luer connector to the female Luer connector of the winged infusion/collection set. Following standard venipuncture protocol, transfer the blood specimen from the patient into the collection tube or sampling bottle.	
Sample collected	Blood, Blood culture	Blood, Blood culture	Same
Biocompatibility	ISO 10993 Compliant including: • Cytotoxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility • Material mediated pyrogenicity	ISO 10993 Compliant including: • Cytotoxicity • Skin sensitization • Intracutaneous Reactivity • Acute System Toxicity • Hemocompatibility • Material mediated pyrogenicity	Same
Sterilization Method	EO with SAL 10^{-6}	EO with SAL 10^{-6}	Same

Comments:

#1: The proposed devices and the predicate device share the same fundamental design and principles of operation. The modifications in the proposed device are limited to a change in the hub material and the inclusion of two additional components: a wider holder and a luer lock cap.

The safety of the new hub material was confirmed through biocompatibility testing conducted in accordance with the requirements of ISO 10993. Furthermore, the two added components are ancillary in nature and do not affect the core technology or performance of the device. Therefore, these changes do not impact its overall safety and effectiveness, supporting the conclusion of substantial equivalence.

#2: The length of between the proposed devices and predicate devices is different. Performance testing results showed that this difference does not affect intended use or the performance of the device. Therefore, these changes do not impact its overall safety and effectiveness, supporting the conclusion of substantial equivalence.

#3: The proposed devices have a broader non-patient cannula size. Performance testing results showed that this difference does not affect intended use or the performance of the device. Therefore, these changes do not impact its overall safety and effectiveness, supporting the conclusion of substantial equivalence.

8. Non-clinical testing

The non-clinical performance tests below were conducted to verify that the proposed devices met all design specifications and performance standards and are each Substantially Equivalent (SE) to the predicate device.

PERFORMANCE TESTING

The proposed device was tested in compliance with ISO 7864 and ISO 9626 for evaluating the overall non-clinical performance. Besides, Luer connector testing in compliance with ISO 80369-7:2021 was conducted to evaluate the performance of connection to hypodermic needle. The performance and design testing results met the standards' requirements to demonstrate the device's safety and effectiveness.

The items listed below underwent testing in accordance with internal testing procedures:

- Luer Torque to break
- Luer Separation force
- Luer Breakage force

BIOCOMPATIBILITY TESTING:

The proposed device was tested in compliance with the 2020 FDA Guidance document Use of International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process”, as the Externally Communicating Device, Blood Path Indirect, Limited Contact (< 24hrs).

The items listed below underwent testing in accordance with ISO 10993-1.

- Cytotoxicity
- Irritation
- Sensitization
- Systemic toxicity
- Hemolysis
- Pyrogen

Meanwhile, Residual particles and Endotoxin were tested in compliance with USP <788> and USP <85>, respectively.

STERILE, PACKAGE AND SHELF-LIFE:

The sterilization process has been validated in compliance with ISO 11135. The EO and ECH residuals do not exceed the limit according to ISO 10993-7.

The Shelf-Life validation study was conducted under accelerated aging condition in compliance with ASTM F1980-16 to verify the claimed shelf-life of 5 years.
Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ASTM D4169-16. All packaging was deemed acceptable for protection of product and sterility maintenance.
Sterile barrier testing was conducted in compliance with the following FDA recognized consensus standards.

- Seal Strength ASTM F88/F88-15
- Dye penetration ASTM F1929-15
- Internal pressure ASTM F1140/F1140M
- Sterility USP <71>

9. Clinical testing

Not applicable for this submission**.**

10. Conclusion

The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.