



November 9, 2023

LILY Medical Corporation  
% Steven Shen  
Senior Manager  
BenQ Medical Technology Corporation  
3F, No. 159, Shan-Ying Road, Shan-Ding Village  
Gueishan Dist.  
Taoyuan, Taiwan 333  
China

Re: K222780

Trade/Device Name: LILY Extension Tube and Needleless Connector  
Regulation Number: 21 CFR 880.5440  
Regulation Name: Intravascular Administration Set  
Regulatory Class: Class II  
Product Code: FPA  
Dated: September 28, 2023  
Received: October 10, 2023

Dear Steven Shen:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "David Wolloscheck". The signature is written in a cursive style. In the background, there is a large, light blue watermark of the letters "FDA".

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

## Indications for Use

510(k) Number (if known)  
K222780

Device Name  
LILY Extension Tube and Needleless Connector

### Indications for Use (Describe)

The LILY Extension Tube and Needleless Connector is a sterile single patient use device for the administration of fluids from a container into the patient's vascular system through a vascular access device. It is for direct injection, continuous or intermittent infusion, aspiration and needle-free delivery of solutions during IV therapy.

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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## K222780 - 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is K222780

Date Prepared: 11/08/2023

### 1. Submitter

LILY Medical Corporation (Manufacturer)

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### 2. Device Information

Device Name: LILY Extension Tube and Needleless Connector

Model:

Device	Model
Needleless Connector	CIC-005S, CIC-006SN, CIC-007NL
Extension Tube	CET-015S, CET-015SD CET-SS02L0, CET-SS02S0 CET-HS03L0, CET-HS03S0, CET-HT03L0, CET-HT03S0

Common Name: IV Administration Set

Classification Name: Intravascular administration set

Regulation Number: 21 CFR 880.5440 /General Hospital (80)

Classification: Class II, Product Code: FPA

### 3. Predicate Device

MaxZero Extension Sets with Needleless Connector (K140831)

#### 4. Device Description

The LILY Extension Tube and Needleless is a closed luer activated device and passively aids in the reduction of needle stick injuries. Fluid flow through the device is activated by the ISO male luer from standard administration set, extension sets and syringes.

The LILY Extension Tube and Needleless Connector provide a solid, sealed, surface for effective disinfection in 3 seconds. It is non-hemolytic. The clear housing and open, fluid filled design of the LILY Extension Tube and Needleless Connector enhance flushing particles. There is less volume of interstitial or dead space internal to the device.

The LILY Extension Tube and Needleless Connector may be used with power injection procedures to a maximum pressure of 325 psi at a flow rate of 10 mL per second.

#### 5. Indications For Use

The LILY Extension Tube and Needleless Connector is a sterile single patient use device for the administration of fluids from a container into the patient's vascular system through a vascular access device. It is for direct injection, continuous or intermittent infusion, aspiration and needle-free delivery of solutions during IV therapy.

#### 6. Intended For Use

The LILY Extension Tube and Needleless Connector is intended for use in the delivery of fluids from a container to a patient's vascular system.

#### 7. Comparison of Technology Characteristics with the Predicate Device

The key technological characteristic of the subject device compared to the Predicate Device is summarized below:

Table 7.1, Technology Characteristics

Characteristic	Subject Device	Predicate Device	Difference Rationale
Device name	LILY Extension Tube and Needleless Connector (K222780)	MaxZero Extension Sets with Needleless Connector (K140381)	
Model	CIC-005S, CIC-006SN, CIC-007NL CET-015S, CET-015SD CET-SS02L0, CET-SS02S0 CET-HS03L0, CET-HS03S0, CET-HT03L0, CET-HT03S0	MZ5301, MZ5302, MZ5303, MZ5304, MZ5305, MZ5306, MZ5307, MZ5308, MZ9284, MZ9285	
Common Name	IV Administration Set	SAME	
Classification	Class II, 21 CFR 880.5440 Set, Administration, Intravascular	SAME	
Product Code	FPA	SAME	
Indication for use	The LILY Extension Tube and Needleless Connector is a sterile single patient use device for the administration of fluids from a container into the patient's vascular system through a vascular access device. It is for direct injection, continuous or intermittent infusion, aspiration and needle-free delivery of solutions during IV therapy.	Pressure Rated: The MaxZero multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10mL per second.  Non Pressure Rated: The MaxZero multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration	
Physical Specification	<ul style="list-style-type: none"> <li>● CIC-005S: Needleless connector (A+)</li> <li>● CIC-006SN: Needleless connector (G2)</li> <li>● CIC-007NL: Needleless connector (G3)</li> <li>● CET-015S: Extension tube, A+ connector, tubing, slide clamp, male luer slip (5.9" Tubing Length, 0.050" Tubing ID, 0.094" Tubing OD)</li> <li>● CET-015SD: Extension tube, A+ connector, tubing, slide clamp, male luer lock (5.9" Tubing Length, 0.050" Tubing ID, 0.094" Tubing OD)</li> <li>● CET-SS02L0: Extension tube, G2 connector, tubing, slide clamp, male luer slip (5.9" Tubing Length, 0.050" Tubing ID, 0.094" Tubing OD)</li> <li>● CET-SS02S0: Extension tube, G2 connector, tubing, slide clamp, male luer lock (5.9" Tubing Length, 0.050" Tubing ID, 0.094" Tubing OD)</li> <li>● CET-HS03L0: Extension tube, G3 connector, tubing, slide clamp, male luer slip (5.9" Tubing Length, 0.040" Tubing ID, 0.094" Tubing OD)</li> <li>● CET-HS03S0: Extension tube, G3 connector, tubing, slide clamp, male luer lock (5.9" Tubing Length, 0.040" Tubing ID, 0.094" Tubing OD)</li> <li>● CET-HT03L0: Extension tube, G3T connector with male luer slip end, tubing, slide clamp, female luer lock (5.9" Tubing Length, 0.040" Tubing ID, 0.094" Tubing OD)</li> <li>● CET-HT03S0: Extension tube, G3T connector with male luer lock end, tubing, slide clamp, female luer lock (5.9" Tubing Length, 0.040" Tubing ID, 0.094" Tubing OD)</li> </ul>	<ul style="list-style-type: none"> <li>● MZ5301: Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock (7" Total Length, 0.042" Tubing ID, 0.079" Tubing OD)</li> <li>● MZ5302: Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock (7" Total Length, 0.042" Tubing ID, 0.079" Tubing OD)</li> <li>● MZ5303: Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock (7" Total Length, 0.060" Tubing ID, 0.144" Tubing OD)</li> <li>● MZ5304: Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock (7" Total Length, 0.060" Tubing ID, 0.144" Tubing OD)</li> <li>● MZ5305: Pressure rated extension set, MaxZero connector, spin male luer lock (7" Total Length, 0.060" Tubing ID, 0.144" Tubing OD)</li> <li>● MZ5306: Pressure rated extension set, minibore tubing, MaxZero connector, spin make luer lock (7" Total Length, 0.042" Tubing ID, 0.079" Tubing OD)</li> <li>● MZ5307: Bi-fuse pressure rated extension set, minibore tubing, (2) MaxZero connectors, (2) slide clamps, spin male luer lock. (7" Total Length, 0.042" Tubing ID, 0.079" Tubing OD)</li> <li>● MZ3508: Bi-fuse pressure rated extension set, minibore tubing, (2) MaxZero connectors, (2) slide clamps, spin make luer lock. (6" Total Length, 0.060" Tubing ID, 0.144" Tubing OD)</li> <li>● MZ9284: Bi-fuse pressure rated extension set, minibore tubing, (2) MaxZero connectors, (2) check valves (2) slide clamps, spin make luer lock (7" Total Length, 0.042" Tubing ID, 0.079" Tubing OD)</li> </ul>	Different <sup>1</sup>

Characteristic	Subject Device	Predicate Device	Difference Rationale
		OD) ● MZ9285: Bi-fuse pressure rated extension set, minibore tubing, (2) MaxZero connectors, (2) check valves (2) slide clamps, spin make luer lock (7" Total Length, 0.060" Tubing ID, 0.144" Tubing OD)	
Priming Volume	<ul style="list-style-type: none"> <li>● CIC-005S: 0.25 mL</li> <li>● CIC-006SN: 0.07 mL</li> <li>● CIC-007NL: 0.04 mL</li> <li>● CET-015S: 0.55 mL</li> <li>● CET-015SD: 0.55 mL</li> <li>● CET-SS02L0: 0.34 mL</li> <li>● CET-SS02S0: 0.34 mL</li> <li>● CET-HS03L0: 0.36 mL</li> <li>● CET-HS03S0: 0.36 mL</li> <li>● CET-HT03L0: 0.36 mL</li> <li>● CET-HT03S0: 0.36 mL</li> </ul>	Avg. 0.66 mL – 0.99 mL	
Residual Volume	<ul style="list-style-type: none"> <li>● CIC-005S: 0.3 mL</li> <li>● CIC-006SN: 0.07 mL</li> <li>● CIC-007NL: 0.04 mL</li> <li>● CET-015S: 0.60 mL</li> <li>● CET-015SD: 0.60 mL</li> <li>● CET-SS02L0: 0.34 mL</li> <li>● CET-SS02S0: 0.34 mL</li> <li>● CET-HS03L0: 0.36 mL</li> <li>● CET-HS03S0: 0.36 mL</li> <li>● CET-HT03L0: 0.36 mL</li> <li>● CET-HT03S0: 0.36 mL</li> </ul>	Unknown	
Gravity Flow rate	<ul style="list-style-type: none"> <li>● CIC-005S: ≥250 mL/min</li> <li>● CIC-006SN: ≥170 mL/min</li> <li>● CIC-007NL: ≥100 mL/min</li> <li>● CET-015S: ≥100 mL/min</li> <li>● CET-015SD: ≥100 mL/min</li> <li>● CET-SS02L0: ≥100 mL/min</li> <li>● CET-SS02S0: ≥100 mL/min</li> <li>● CET-HS03L0: ≥75 mL/min</li> <li>● CET-HS03S0: ≥75 mL/min</li> <li>● CET-HT03L0: ≥75 mL/min</li> <li>● CET-HT03S0: ≥75 mL/min</li> </ul>	≥100 mL/min	<b>Different<sup>2</sup></b>
Flush Volume	<ul style="list-style-type: none"> <li>● CIC-005S: 5mL</li> <li>● CIC-006SN: 3mL</li> <li>● CIC-007NL: 1.5mL</li> <li>● CET-015S: 5mL</li> <li>● CET-015SD: 5mL</li> <li>● CET-SS02L0: 3mL</li> <li>● CET-SS02S0: 3mL</li> <li>● CET-HS03L0: 3mL</li> <li>● CET-HS03S0: 3mL</li> <li>● CET-HT03L0: 3mL</li> <li>● CET-HT03S0: 3mL</li> </ul>	5 mL	
Displacement	<ul style="list-style-type: none"> <li>● CIC-005S: ≤0.05 mL</li> <li>● CIC-006SN: ≤0.003 mL</li> <li>● CIC-007NL: ≤0.001 mL</li> <li>● CET-015S: ≤0.05 mL</li> <li>● CET-015SD: ≤0.05 mL</li> <li>● CET-SS02L0: ≤0.003 mL</li> <li>● CET-SS02S0: ≤0.003 mL</li> <li>● CET-HS03L0: ≤0.001 mL</li> </ul>	~Zero (16uL)	

Characteristic	Subject Device	Predicate Device	Difference Rationale
	<ul style="list-style-type: none"> <li>● CET-HS03S0: ≤0.001 mL</li> <li>● CET-HT03L0: ≤0.001 mL</li> <li>● CET-HT03S0: ≤0.001 mL</li> </ul>		
Power Infusion Flow Rate	10mL/sec @325 PSI	SAME	
Hemolysis	No-Hemolytic	SAME	
Use	Single Patient	SAME	
Duration of Use	7 Days	SAME	
Number of Activations	<ul style="list-style-type: none"> <li>● CIC-005S: 200</li> <li>● CIC-006SN: 600</li> <li>● CIC-007NL: 600</li> <li>● CET-015S: 200</li> <li>● CET-015SD: 200</li> <li>● CET-SS02L0: 600</li> <li>● CET-SS02S0: 600</li> <li>● CET-HS03L0: 600</li> <li>● CET-HS03S0: 600</li> <li>● CET-HT03L0: 600</li> <li>● CET-HT03S0: 600</li> </ul>	200	<b>Different<sup>3</sup></b>
Method of Disinfection	70% IPA	SAME	
Sterilization Method	Ethylene Oxide	E-beam (Radiation)	<b>Different<sup>4</sup></b>
Provided Sterile	Yes	SAME	
Sterile Barrier Packaging	Medical-Grade Papers; Heat-Sealed	Tyvek Polyethylene; Heat-Sealed	<b>Different<sup>5</sup></b>
Packaged Quantity	Single Unit Per Package	SAME	

**Different<sup>1</sup>**

The Physical Specification of subject device is different from the predicate device. The subject device consist of needleless connector and extension set with needleless connector. The predicate device consist of extension set with needleless connector only. Both subject device and predicate device on extension set have similar configuration consists of needleless connector, tubing, slide clamps, and male luer connector.

The subject device has been evaluated in performance tests including biocompatibility and bench testing (functional testing) in support of the substantial equivalence determination. The two devices have similar technical characteristics and physical properties, with no new or different questions of safety or effectiveness being raised that would affect the substantial equivalence of the two devices.

In order to ensure the end user to know the differences in technological characteristics of the subject device, the physical specification including components, tubing length and ID/OD are specified in User Manual.

Table 7.2, LILY Extension Tube and Needleless Connector Description

Model	Components	Tubing Length	Tubing ID	Tubing OD
CIC-005S	Needleless Connector (A+), Vented Male Luer Cap	NA	NA	NA
CIC-006SN	Needleless Connector (G2), Vented Male Luer Cap	NA	NA	NA
CIC-007NL	Needleless Connector (G3), Vented Male Luer Cap	NA	NA	NA

Model	Components	Tubing Length	Tubing ID	Tubing OD
CET-015S	Needleless Connector (A+), Female Luer Lock, Tubing, Male Luer Slip, Vented Male Luer Cap	5.9" (150mm)	0.050" (1.27mm)	0.094" (2.4mm)
CET-015SD	Needleless Connector (A+), Female Luer Lock, Tubing, Slide Clamp, Male Luer Lock, Vented Male Luer Cap	5.9" (150mm)	0.050" (1.27mm)	0.094" (2.4mm)
CET-SS02L0	Needleless Connector (G2), Tubing, Slide Clamp, Male Luer Slip, Vented Male Luer Cap	5.9" (150mm)	0.050" (1.27mm)	0.094" (2.4mm)
CET-SS02S0	Needleless Connector (G2), Tubing, Slide Clamp, Male Spin Lure Lock Assembly, Vented Male Luer Cap	5.9" (150mm)	0.050" (1.27mm)	0.094" (2.4mm)
CET-HS03L0	Needleless Connector (G3), Female Luer Lock, Tubing, Slide Clamp, Male Luer Slip, Vented Male Luer Cap	5.9" (150mm)	0.040" (1 mm)	0.094" (2.4mm)
CET-HS03S0	Needleless Connector (G3), Female Luer Lock, Tubing, Slide Clamp, Male Spin Lure Lock Assembly, Vented Male Luer Cap	5.9" (150mm)	0.040" (1 mm)	0.094" (2.4mm)
CET-HT03L0	Needleless Connector (G3T), Vented Male Luer Cap, Tubing, Slide Clamp, Female Luer Lock, Non-Vented Female Luer Cap	5.9" (150mm)	0.04" (1 mm)	0.094" (2.4mm)
CET-HT03S0	Needleless Connector (G3T), Nut, Vented Male Luer Cap, Tubing, Slide Clamp, Female Luer Lock, Non-Vented Female Luer Cap	5.9" (150mm)	0.04" (1 mm)	0.094" (2.4mm)

**Different<sup>2</sup>**

The Priming Volume, Gravity Flow rate, Flush Volume, Displacement of subject device are different from the predicate device, but the Residual Volume of the predicate device is unknown. These minor differences in technological characteristics between the subject device and predicate device do not raise new issues of safety or effectiveness. The LILY Extension Tube and Needleless Connector has been evaluated performance testing according to specified standard of IV Administration Set.

In order to ensure the end user to know the differences in technological characteristics of the subject device, the Priming Volume, Residual Volume, Gravity Flow rate, Flush Volume, and Displacement of subject device are described in User Manual.

**Different<sup>3</sup>**

The Duration of Use and Number of Activations times of subject device are different from the predicate device. The subject device has undergone microbial ingress testing, and the test results demonstrate the model of CIC-005S, CET-015S, and CET-015SD can be used for 7 days and 200 activations, the others can be used for 7 days and 600 activations. Therefore, the difference will not affect the safety and effectiveness of the subject device.

In addition, in order to ensure the end user to know the Duration of Use and Number of Activations times of the subject device, the service time and activation times of subject device are described in User Manual.

**Different<sup>4</sup>**

The LILY Extension Tube and Needleless Connector is ethylene oxide gas sterilized compared to the predicate device which is sterilized by radiation. Both methods of sterilization are widely used in the medical device industry and utilize FDA recognized standards for sterilization validation. Both devices are functionally evaluated after all manufacturing processes including exposure to sterilization conditions which demonstrates no issues of safety or effectiveness.

**Different<sup>5</sup>**

The package of LILY Extension Tube and Needleless Connector is Medical-Grade Papers in Heat-Sealed compared to the predicate device which is Tyvek Polyethylene in Heat-Sealed. Both materials are considered for use in medical packaging, the Seal Strength, Dye Penetration, Burst Test & Creep Test are evaluated after all manufacturing processes including exposure to sterilization conditions which demonstrates no issues of safety or effectiveness.

8. Performance Testing

The following non-clinical data were provided in support of the substantial equivalence determination:

Biocompatibility:

Conducted per Guidance Document “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”; Guidance for Industry and Food and Drug Administration Staff, Jun 16, 2016 and “Guidance for Industry and FDA Staff – Intravascular Administration Sets Premarket Notification Submissions [510(k)],” July 11, 2008, as recognized by the FDA. Biocompatibility testing was conducted in accordance with the cited guidance and standards as required for an External Communicating Device, Blood Path Direct Contact (Infusion Only), Prolonged Duration.

Table 8.1, Biocompatibility Testing

Test	Standard	Result
Cytotoxicity	FDA Recognition Number 2-245, ISO 10993-5: 2009, Biological Evaluation of Medical Devices Part 5: Tests for in vitro Cytotoxicity	<b>Pass</b> - No reactivity
Sensitization	FDA Recognition Number 2-296, ISO 10993-10: 2021, Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	<b>Pass</b> – Non-sensitizing
Intracutaneous reactivity Irritation in Rabbits	FDA Recognition Number 2-291, ISO 10993-23:2021, Biological Evaluation Of Medical Devices - Part 23: Tests For Irritation	<b>Pass</b> – Non-irritant
Acute Systemic Toxicity	FDA Recognition Number 2-255, ISO 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity	<b>Pass</b> – Did not cause acute systemic toxicity
Subacute Toxicity		<b>Pass</b> – Did not cause Subacute Toxicity
Hemo-compatibility	FDA Recognition Number 2-248, ISO 10993-4: 2017, Biological evaluation of medical devices Part 4: Tests for Interactions with Blood	<b>Pass</b> –Hemo-compatibility
Hemolysis	FDA Recognition Number 2-250, ASTM F 756 – 17: Standard Practice for Assessment of Hemolytic Properties of Materials	<b>Pass</b> – Non-hemolytic
Pyrogenicity	USP <40>Pyrogen Test Procedure, Section <151>	<b>Pass</b> – Non-pyrogenic
Endotoxin (Limulus amebocyte lysate test)	USP <161>, Medical Devices—Bacterial Endotoxin and Pyrogen Tests	<b>Pass</b> - Less than 20 EU per device

Bench Testing (Functional Testing):

The following bench testing was conducted on the LILY Extension Tube and Needleless Connector to determine the subject device is substantially equivalent to the predicate device.

Table 8.2, Functional Testing

Test	Standard	Result
Sterility	FDA Recognition Number 14-529, ISO 11135:2014/AMD 1:2018 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release  FDA Recognition Number 2-275, ISO 10993-7:2008/Amd	<b>Pass</b>

Test	Standard	Result
	1:2019 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals — Amendment 1: Applicability of allowable limits for neonates and infants	
3 Year Shelf Life	<p>FDA Recognition Number 14-497, ASTM F1980-16: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices</p> <p>FDA Recognition Number 14-530, ISO 11607-1 Second Edition 2019-02: Packaging for terminally sterilized medical devices – Part 1. Requirements for materials, sterile barrier systems, and packaging systems</p>	<b>Pass</b>
<p>FDA Guidance Compliance:</p> <ul style="list-style-type: none"> <li>– Resistance to Separation from Axial Load</li> <li>– Resistance to Separation from Unscrewing</li> <li>– Resistance to Overriding</li> <li>– Stress Cracking</li> <li>– Pressure Liquid Leakage</li> <li>– Subatmospheric-Pressure Air Leakage</li> <li>– Backpressure</li> <li>– IPA Exposure</li> <li>– Infusate Compatibility</li> <li>– Duration of Activation</li> <li>– Number of Activations</li> <li>– Flow Rate</li> <li>– Priming Volume</li> <li>– Residual Volume</li> <li>– Flush Volume</li> <li>– Displacement</li> <li>– Power Injection</li> <li>– Hemolysis</li> <li>– Microbial Ingress</li> <li>– Tensile Strength</li> <li>– Particulate Contamination</li> <li>– Reducing (oxidizable) Matter</li> <li>– Metal Ions</li> <li>– Titration Acidity or Alkalinity</li> <li>– Residue on Evaporation</li> <li>– UV Absorption of Extract Solution</li> </ul>	<p>FDA Guidance: Intravascular Administration Sets Premarket Notification Submission [510(k)]: 2008</p> <p>FDA Recognition Number 6-481, AAMI ANSI CN27:2021, General requirements for Luer activated valves (LAVs) incorporated into medical devices for intravascular applications</p> <p>FDA Recognition Number 6-447, ISO 8536-4:2019, Infusion equipment for medical use —Part 4:Infusion sets for single use, gravity feed</p> <p>FDA Recognition Number 5-133, ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications</p> <p>FDA Recognition Number 5-97, ISO 80369-20:2015, Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods</p> <p>USP &lt;788&gt; Particulate Contamination</p>	<b>Pass</b>

9. Clinical Studies

No clinical study is included in this submission.

10. Conclusion

The conclusions drawn from the performance testing tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.