August 27, 2024

Nemoto Kyorindo Co., Ltd.
% Dave Yungvirt, CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K242212
Trade/Device Name: Disposable Syringe (Kit); Nemoto Disposable Syringe (Kit)
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: DXT
Dated: July 26, 2024
Received: July 29, 2024

Dear Dave Yungvirt:

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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
Division of Drug Delivery and General
Hospital Devices, and Human Factors
Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242212

Device Name
Disposable Syringe (Kit); Nemoto Disposable Syringe (Kit)

Indications for Use *(Describe)*

100 mL/200 mL Syringe:
The Disposable Syringe (Kit) (100 mL or 200 mL Syringe) is a syringe for the injection of contrast media orsaline for CT and MR imaging, for use on Nemoto injectors.

150 mL Syringe:
The Disposable Syringe (Kit) (150 mL Syringe) is a syringe for the injection of contrast media or saline forangiography, for use on Nemoto injectors.

J-Tube:
J-Tube is to aid in transferring a media from its container (typically a vial or bottle) into the barrel of thesyringe of the Disposable Syringe (Kit).

Extension Tubes:
The Extension Tube is to provide a connection between the syringe barrel and the needle or catheter that is punctured into the patient.

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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K242212 510(k) Summary

Disposable Syringe (Kit), Nemoto Disposable Syringe (Kit)

1. Submission Sponsor

Nemoto Kyorindo Co., Ltd.
2-27-20 Hongo, Bunkyo-ku,
Tokyo, 113-0033 Japan Contact:
Jim Knipfer
Title: GM, Overseas Department
Office Phone: +81 3 5842 8571
Email: jim@nemoto-do.co.jp

2. Submission Correspondent

Nemoto Kyorindo Co., Ltd.
2-27-20 Hongo, Bunkyo-ku,
Tokyo, 113-0033 Japan Contact:
Jim Knipfer
Title: GM, Overseas Department
Office Phone: +81 3 5842 8571
Email: jim@nemoto-do.co.jp

3. Date Prepared

July 26, 2024

4. Device Identification

Trade/Proprietary Name:	Disposable Syringe (Kit), Nemoto Disposable Syringe (Kit)
Classification Name:	Injector and Syringe, Angiographic
Regulation Number(s):	870.1650
Product Code(s):	DXT
Class:	II
Classification Panel:	Cardiovascular

5. Legally Marketed Predicate Device(s)

Device name: Disposable CT/MR Syringes for Nemoto Injectors
510(k) number: K051799
Manufacturer: Coeur Inc.

Device name: Disposable Angiographic Syringes for Nemoto Injectors
510(k) number: K090487
Manufacturer: Coeur Inc.

Device name: Disposable 330 psi extension lines
510(k) number: K120892
Manufacturer: Coeur Inc.

6. Device Description

The "Disposable Syringe (Kit)" (Subject Device) is specifically designed for use with the Nemoto power injection systems marketed and sold in the USA using 510(k) references K133189, K071691, K173450, K092896, K091734. The Subject Device is a package provided to the end user that contains one or two plastic syringes, plastic tubing used for connecting syringe to needle or catheter (Extension Tubing) and a plastic J-shaped tube for transferring contrast media or physiological saline into the plastic syringe (J-Tube). The Subject Device, in accordance with the Indications for Use, may be used in conjunction with CT or MRI applications or in conjunction with angiographic applications. The key difference in the application as it relates to the Subject Device is the pressure required and the flow rates required for the Subject Device. The Subject Device when used for the CT and MRI applications must support a maximum pressure of 300PSI and a maximum flow rate of 10mL/second. The Subject Device when used for the angiographic applications must support a maximum pressure of 1200PSI and a maximum flow rate of 30mL/second. The maximum values related to the application are controlled by the Nemoto power injection system which are fully described in the aforementioned 510(k)s.

7. Indication for Use Statement

100 mL/200 mL Syringe:

The Disposable Syringe (Kit) (100 mL or 200 mL Syringe) is a syringe for the injection of contrast media or saline for CT and MR imaging, for use on Nemoto injectors.

150 mL Syringe:

The Disposable Syringe (Kit) (150 mL Syringe) is a syringe for the injection of contrast media or saline for angiography, for use on Nemoto injectors.

J-Tube:

J-Tube is to aid in transferring a media from its container (typically a vial or bottle) into the barrel of the syringe of the Disposable Syringe (Kit).

Extension Tubes:
The Extension Tube is to provide a connection between the syringe barrel and the needle or catheter that is punctured into the patient.

7.1 Intended users

To be used by medical professionals who are trained and qualified to deliver contrast media or normal saline into adult patients. Prescription Use Only.

8. Substantial Equivalence Discussion

The following table compares the Disposable Syringe (Kit) to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Comparison of Characteristics (100 mL or 200 mL Syringe)

Attribute	**SUBJECT DEVICE**	**Predicate: Disposable CT/MR Syringes for Nemoto Injectors**	**Comparison**
510(k) Number	-	K051799	-
Product Code	DXT	DXT	Same
Regulation Number	870.1650	870.1650	Same
Indications for Use	The Nemoto Disposable Syringe (Kit) is specifically designed for use with Nemoto Injectors and are intended to be used for the administration of contrast media or physiological saline into a patient in conjunction with CT and MR examinations.	The Disposable CT/MR Syringe for Nemoto Injectors is a syringe for the injection of contrast media or saline for CT and MR imaging, for use on Nemoto injectors	Same meaning
Intended users	To be used by medical professionals who are trained and qualified to deliver contrast media or normal saline into adult	To be used by medical professionals who are trained and qualified to deliver contrast media or normal saline into adult	Same

Attribute	SUBJECT DEVICE	Predicate: Disposable CT/MR Syringes for Nemoto Injectors	Comparison
	patients. Prescription Use Only.	patients. Prescription Use Only.	
Syringe type/Environment od use	CT and MRI applications	CT and MRI applications	Same
Specific drug use	Contrast media or saline	Contrast media or saline	Same
Volume	100 mL, 200 mL	20 mL, 50 mL, 100 mL and 200mL	The predicate device includes volumes of the subject device.
Length/mm	100 mL Syringe: Barrel length: 153.21 200 mL Syringe: Barrel length: 157.81	100 mL Syringe: Barrel length: 153.21 200 mL Syringe: Barrel length: 157.81	Same
Diameter	100 mL Syringe: Outer diameter: 49.60-49.70 Inner diameter: 45.90-46.00 200 mL Syringe: Outer diameter: 31.95-32.05 Inner diameter: 35.39-35.61	100 mL Syringe: Outer diameter: 49.60-49.70 Inner diameter: 45.90-46.00 200 mL Syringe: Outer diameter: 31.95-32.05 Inner diameter: 35.39-35.61	Same
Nozzle type	ISO 80369-7: 2021 compliant	ISO 594 compliant	Same ISO 594 was replaced by ISO 80369-7.
Pressure Limit	Up to 300psi	Up to 300psi	Same
Particle matter	ISO 7886-1:2017 compliant	Meets visual inspection requirements	Equivalent, ISO 7886-1 requires visual check.
Chemical test (Extractable metals and Limits for acidity or alkalinity)	ISO 7886-1:2017 compliant	ISO 7886-1:1993 compliant	Same standard applied
Tolerance on graduated capacity	ISO 7886-1:2017 compliant	ISO 7886-1:1993 compliant	Same standard applied

Attribute	SUBJECT DEVICE	Predicate: Disposable CT/MR Syringes for Nemoto Injectors	Comparison
Scale	ISO 7886-1:2017 compliant	ISO 7886-1:1993 compliant	Same standard applied
Numbering of scales	ISO 7886-1:2017 compliant	ISO 7886-1:1993 compliant	Same standard applied
Overall length of scale to nominal capacity line	ISO 7886-1:2017 compliant	ISO 7886-1:1993 compliant	Same standard applied
Position of scale	ISO 7886-1:2017 compliant	ISO 7886-1:1993 compliant	Same standard applied
Barrel	ISO 7886-1:2017 compliant	While syringe is technically ISO 7886-1:1993 compliant by Design of flange, the syringe is intended for use with injector.	Same standard applied
Plunger stopper/plunger assembly	ISO 7886-1:2017 compliant	N/A – Syring is intended for use with injector.	While the predicate device does not apply ISO 7886-1 but, what the subject device complies with ISO 7886-1 does not raise additional risk.
Nozzle lumen	ISO 7886-1:2017 compliant	ISO 7886-1:1993 compliant	Same standard applied
Dead space	ISO 7886-1:2017 compliant	ISO 7886-1:1993 compliant	Same standard applied
Freedom from air and liquid leakage past plunger stopper	Freedom from air: ISO 7886-1:2017 compliant Liquid leakage past plunger stopper: Pressure resistance testing (300 psi)	ISO 7886-1:1993 compliant	Same standard applied
Fit of plunger stopper/plunger in barrel	ISO 7886-1:2017 compliant	ISO 7886-1:1993 compliant	Same standard applied

Attribute	SUBJECT DEVICE	Predicate: Disposable CT/MR Syringes for Nemoto Injectors	Comparison
Materials	Thermoplastic Vulcanizate Poly Cyclohexylenedimethylene Terephthalate glycol-modified (PCTG) Polypropylene Silicone	PET	The subject device complies with biocompatibility, ISO 7886-1 and pressure limit testing that is appropriate.
Sterility	EtO Sterilized	EtO Sterilized	Same
Single-Use	Single use	Single use	Same
Shelf Life	5 years	5 years	Same
Complies with ISO 10993-1	Compliance	Compliance	Same

Comparison of Characteristics (150 mL Syringe)

Attribute	SUBJECT DEVICE	Predicate: Disposable Angiographic Syringes for Nemoto Injectors	Comparison
510(k) Number	-	K090487	-
Product Code	DXT	DXT	Same
Regulation Number	870.1650	870.1650	Same
Indications for Use	The Nemoto Disposable Syringe (Kit) is specifically designed for use with Nemoto Injectors and are intended to be used for the administration of contrast media or physiological saline into a patient in conjunction with angiographic examinations.	for injecting contrast media and saline, for angiography	Same meaning
Intended users	To be used by medical professionals who are trained and qualified to deliver contrast media or normal saline into adult	To be used by medical professionals who are trained and qualified to deliver contrast media or normal saline into adult	Same

Attribute	SUBJECT DEVICE	Predicate: Disposable Angiographic Syringes for Nemoto Injectors	Comparison
	patients. Prescription Use Only.	patients. Prescription Use Only.	
Syringe type/Environment od use	Angiographic application	Angiographic application	Same
Specific drug use	Contrast media or saline	Contrast media or saline	Same
Volume	150 mL	150 mL	Same
Length/mm	Barrel: 141 mm Overall: 239.8 mm	Barrel: 141 mm Overall: 239.8 mm	Same
Diameter	O.D. 43.52 mm I.D. 40.2 mm	O.D. 43.52 mm I.D. 40.2 mm	Same
Nozzle type	Luer male connector, ISO 80369-7: 2021 compliant	Luer connection, ISO 594 compliant	Same ISO 594 was replaced by ISO 80369-7.
Pressure Limit	Up to 1200 psi	Up to 1200 psi	Same
Particle matter	ISO 7886-1:2017 compliant	ISO7886-1:1993	Same standard applied
Chemical test (Extractable metals and Limits for acidity or alkalinity)	ISO 7886-1:2017 compliant	ISO7886-1:1993	Same standard applied
Barrel	ISO 7886-1:2017 compliant	ISO7886-1:1993	Same standard applied
Pressure resistance	1200 psi compliant	1200 psi compliant	Same
Materials	Polycarbonate, Polypropylene, Polyoxymethylene (POM), Silicone	Polypropylene, Silicone	The subject device complies with biocompatibility, ISO 7886-1 and pressure limit testing that is appropriate.
Sterility	EtO Sterilized	EtO Sterilized	Same
Single-Use	Single use	Single use	Same
Shelf Life	5 years	5 years	Same
Complies with ISO 10993-1	Compliance	Compliance	Same

Comparison of Characteristics (Extension Tubes)

Attribute	SUBJECT DEVICE	Predicate: Disposable 330 psi extension lines	Comparison
510(k) Number	-	K120892	-
Product Code	DXT	DXT	Same
Regulation Number	870.1650	870.1650	Same
Indications for Use	The Extension Tube is to provide a connection between the syringe barrel and the needle or catheter that is punctured into the patient.	To be used as an interface between (an) Angiographic, CT, or MR Syringe(s) and a needle catheter for the purpose of delivering diagnostic fluids (such as contrast media and saline) to the vascular system.	Same meaning
Intended users	To be used by medical professionals who are trained and qualified to deliver contrast media or normal saline into adult patients. Prescription Use Only.	To be used by medical professionals who are trained and qualified to deliver contrast media or normal saline into adult patients. Prescription Use Only.	Same
Syringe type/Environment od use	CT and MRI applications	CT, MRI, and Angio applications	The predicate device includes environment of use of the subject device
Specific drug use	Contrast media or saline	Contrast media or saline	Same
Length/mm	1500 mm / 1550 mm	1500 mm / 1550 mm	Same
Diameter	O.D.: 3.25-3.33 mm I.D.: 1.77-1.85 mm	O.D.: 3.87-3.95 mm I.D.: 2.31-2.39 mm *Manually measured	Different, but the subject device complies with ISO 8536-9, Infusion equipment for medical use – part 9: fluid lines for single use with pressure infusion

Attribute	SUBJECT DEVICE	Predicate: Disposable 330 psi extension lines	Comparison
			equipment, and pressure limit testing that is appropriate.
Connector type	ISO 80369-7: 2021 compliant	ISO 594 compliant	Same ISO 594 was replaced by ISO 80369-7.
Pressure Limit	300 psi	330 psi	Nominal pressure is different, however, the compatible injector can apply pressure up to 300 psi and there is no additional risk raised.
Transparency	ISO 8536-9:2015 compliance	Allows clear view	The same visual testing
Particulate contamination	ISO 8536-9:2015 compliance	Visual inspection	The subject device was conducted more severe testing and no additional risk is raised.
Tensile strength	ISO 8536-9:2015 compliance	Must hold 8lb for a minimum of 10 seconds without breakage of the bond or the tubing	The subject device complies with current ISO standard and does not raise additional risk.
Leakage	Air leakage: ISO 8536-9:2015 compliance Water leakage: Pressure resistance testing (300 psi)	Air leakage requirement – 2psi without leakage Water leakage: Pressure resistance testing (330 psi)	Air leakage: The subject device complies with current ISO

Attribute	SUBJECT DEVICE	Predicate: Disposable 330 psi extension lines	Comparison
			standard and does not raize additional risk. Water leakage: Nominal pressure is different, however, the compatible injector can apply pressure up to 300 psi and there is no additional risk raised.
Material	Poly Vinyl Chloride (PVC), High Density Polyethylene (HDPE), Low Density Polyethylene (LDPE), Polypropylene, Poly Carbonate (PC)	No information	The subject device complies with biocompatibility, ISO 8536-9 and pressure limit testing that is appropriate.
Sterility	EtO Sterilized	EtO Sterilized	Same
Single-Use	Single use	Single use	Same
Shelf Life	5 years	5 years	Same
Complies with ISO 10993-1	Compliance	Compliance	Same

Comparison of Characteristics (J-Tube)

Attribute	SUBJECT DEVICE	Predicate: Disposable Angiographic Syringes for Nemoto Injectors	Comparison
510(k) Number	-	K090487	-
Product Code	DXT	DXT	Same
Regulation Number	870.1650	870.1650	Same

Attribute	SUBJECT DEVICE	Predicate: Disposable Angiographic Syringes for Nemoto Injectors	Comparison
Indications for Use	J-Tube is to aid in transferring a media from its container (typically a vial or bottle) into the barrel of the syringe of the Disposable Syringe (Kit).	for injecting contrast media and saline, for angiography	The indications for use of the predicate device is described in general including syringes and tubing., but no additional concerns for safety and effectiveness of the subject device since J-Tube performs just as transferring a contrast media or saline and the component of the predicate device performs as the same.
Intended users	To be used by medical professionals who are trained and qualified to deliver contrast media or normal saline into adult patients. Prescription Use Only.	To be used by medical professionals who are trained and qualified to deliver contrast media or normal saline into adult patients. Prescription Use Only.	Same
Syringe type/Environment od use	CT and MRI applications	CT, MRI, and Angio applications	The predicate device includes environment of use of the subject device
Specific drug use	Contrast media or saline	contrast media or saline	Same
Length/mm	190 mm	Approximately 190 mm	Same
Diameter	O.D.: 5.8 mm + 0.15 mm I.D.: 4.0 mm + 0.1 mm	OD: 5.6mm ID: 4.2mm	Slightly different, but the

Attribute	SUBJECT DEVICE	Predicate: Disposable Angiographic Syringes for Nemoto Injectors	Comparison
			difference does not raise any risk since the J-Tube is to be used to transfer a media from its container into the barrel of the syringe.
Connector type	Luer-slip connection, ISO 80369-7: 2021 compliant	Luer-slip connection	Same
Connection force	More than 0.51 kgf (5 N)	Not specified	Different, however, this force is sufficient to prevent disconnection between J tube and syringe which cause failure of media transfer, which could cause delay of procedure but no injury to patients.
Materials	Low Density Polyethylene (LDPE)	Polyethylene	Different, however, biocompatibility and connection verification between the J-Tube and the Disposable syringes are completed. There is no additional

Attribute	SUBJECT DEVICE	Predicate: Disposable Angiographic Syringes for Nemoto Injectors	Comparison
			concerns for safety and effectiveness of the subject device.
Sterility	EtO Sterilized	EtO Sterilized	Same
Single-Use	Single use	Single use	Same
Shelf Life	5 years	5 years	Same
Complies with ISO 10993-1	Compliance	Compliance	Same

9. Non-Clinical Performance Data

To support substantial equivalence to the predicate device, Nemoto Kyorindo Co., Ltd. completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met.

The Disposable Syringe (Kit) passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its substantial equivalence to the predicate device:

- Cytotoxicity testing per ISO 10993-5 – Passed
- Sensitization testing per ISO 10993-10 – Passed
- Irritation testing per ISO 10993-23 – Passed
- Acute systemic toxicity testing per ISO 10993-11 – Passed
- Hemolysis testing per ISO 10993-4, ASTM F 756 – Passed
- Pyrogenicity testing per ISO 10993-11, USP-NF 38 <151> Pyrogen Test – Passed
- Particulate Contamination testing per USP <788> – Passed
- Endotoxin testing per USP-NF <85> and <161> – Passed
- Lubricant testing per modified ISO 7886-1 – Passed
- Tolerance on Graduated Capacity testing per ISO 7886-1 – Passed
- Scale testing per ISO 7886-1 – Passed
- Numbering of Scales testing per ISO 7886-1 – Passed
- Overall length of scale to nominal capacity line per ISO 7886-1 – Passed
- Position of Scale testing per ISO 7886-1 – Passed

- Barrel testing per ISO 7886-1 – Passed
- Plunger Stopper/Plunger Assembly testing per ISO 7886-1 – Passed
- Nozzle Lumen testing per ISO 7886-1 – Passed
- Dead Space testing per ISO 7886-1 – Passed
- Freedom from Air past Plunger Stopper testing per ISO 7886-1 – Passed
- Fit of Plunger Stopper/Plunger in Barrel per ISO 7886-1 – Passed
- Liquid Leakage past Plunger Stopper testing per in-house pressure resistance testing – Passed
- Transparency testing per ISO 8536-9 – Passed
- Tensile Strength testing per ISO 8536-9 – Passed
- Leakage testing per ISO 8536-9 – Passed
- Injection Needle testing per ISO 8536-9 – Passed
- Chemical testing per ISO 7886-1, ISO 8536-9 – Passed
- Connection force per in-house testing – Passed
- Positive Pressure Liquid Leakage testing per ISO 80369-7 – Passed
- Sub-Atmospheric Pressure Air Leakage testing per ISO 80369-7 – Passed
- Stress Cracking testing per ISO 80369-7 – Passed
- Resistance to Separation from Axial Load testing per ISO 80369-7 – Passed
- Resistance to Separation from Unscrewing testing per ISO 80369-7 – Passed
- Resistance to Overriding testing per ISO 80369-7 – Passed
- Compatibility per in-house testing – Passed
- Sterilization validation – demonstrates SAL of 10^{-6}
- Ethylene Oxide Sterilization Residuals testing per ISO 10993-7 – Passed
- Shelf Life Testing – Supports shelf life of 5 years
- Transportation Testing per ASTM F88/88M, ASTM F1140/F1140M, ASTM F1929, ASTM F1886/F1886M and ISO 11607-1 – Demonstrates package integrity maintained
- Usability Engineering per IEC 62366-1 – Evaluated

10. Clinical Performance Data

No clinical data was necessary to determine the substantial equivalence of this device.

11. Statement of Substantial Equivalence

The Disposable Syringe (Kit) has the same indications for use as the predicate devices listed above. Any minor differences in the technological characteristics of the subject device when compared to the predicate devices have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any

new questions of safety and effectiveness. Therefore, the Disposable Syringe (Kit) has been determined to be substantially equivalent to the predicate devices.