May 14, 2026

Fortis Biosolutions Company Limited
Sharon Au
Project Engineer, Regulatory Affairs
No. 121, Lane 215, Gaoyang S. Rd.
Longtan Dist.,
Taoyuan City, 325004, Taiwan

Re: K252652
Trade/Device Name: Disposable Syringes with Accessories for Power Injectors (900103T); Disposable Syringes with Accessories for Power Injectors (900103H); Disposable Syringes with Accessories for Power Injectors (801800H); Disposable Syringes with Accessories for Power Injectors (800099T); Disposable Syringes with Accessories for Power Injectors (800099H); Disposable Syringes with Accessories for Power Injectors (800096T); Disposable Syringes with Accessories for Power Injectors (800096H); Disposable Syringes with Accessories for Power Injectors (844023T); Disposable Syringes with Accessories for Power Injectors (844023H); Disposable Syringes with Accessories for Power Injectors (844022T); Disposable Syringes with Accessories for Power Injectors (844022H)
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: August 22, 2025
Received: March 27, 2026

Dear Sharon Au:

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,

Shruti N. Mistry -S

Shruti Mistry
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

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252652 |

Please provide the device trade name(s).

Disposable Syringes with Accessories for Power Injectors (900103T);
Disposable Syringes with Accessories for Power Injectors (900103H);
Disposable Syringes with Accessories for Power Injectors (801800H);
Disposable Syringes with Accessories for Power Injectors (800099T);
Disposable Syringes with Accessories for Power Injectors (800099H);
Disposable Syringes with Accessories for Power Injectors (800096T);
Disposable Syringes with Accessories for Power Injectors (800096H);
Disposable Syringes with Accessories for Power Injectors (844023T);
Disposable Syringes with Accessories for Power Injectors (844023H);
Disposable Syringes with Accessories for Power Injectors (844022T);
Disposable Syringes with Accessories for Power Injectors (844022H)

Please provide your Indications for Use below.

The proposed device is intended for the injection of contrast media or saline; it shall be used with US legally marketed angiographic injectors.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

# K252652 510(k) Summary

1. **Type of Submission:** Traditional

2. **Date of Summary:** May 14, 2026

3. **Submitter information**

| | |
|---|---|
| **Name:** | Fortis Biosolutions Company Limited |
| **Address:** | No. 121, Ln. 215, Gaoyang S. Rd., Longtan Dist., Taoyuan City 325, Taiwan (R.O.C.) |
| **Phone:** | +886-3-4710089 ext. 203 |
| **Correspondent:** | Sharon Au ( sharon_au@fortisbios.com ) |

4. **Identification of the subject device**

**Trade Name:**

Disposable Syringes with Accessories for Power Injectors (900103T);
Disposable Syringes with Accessories for Power Injectors (900103H);
Disposable Syringes with Accessories for Power Injectors (801800H);
Disposable Syringes with Accessories for Power Injectors (800099T);
Disposable Syringes with Accessories for Power Injectors (800099H);
Disposable Syringes with Accessories for Power Injectors (800096T);
Disposable Syringes with Accessories for Power Injectors (800096H);
Disposable Syringes with Accessories for Power Injectors (844023T);
Disposable Syringes with Accessories for Power Injectors (844023H);
Disposable Syringes with Accessories for Power Injectors (844022T);
Disposable Syringes with Accessories for Power Injectors (844022H)

| | |
|---|---|
| **Review Panel:** | General Hospital |
| **Regulation Medical Specialty:** | Cardiovascular |
| **Regulation Number:** | 21 CFR 870.1650 |
| **Regulation Description:** | Angiographic injector and syringe |
| **Product Code:** | DXT |
| **Device Class:** | Class II |

## 5. Identification of the predicate device

| | |
|---|---|
| **510(k) Number:** | K192657 |
| **Predicate Trade Name:** | Sterile High-pressure Angiographic Syringes for Single-use |
| **Applicant:** | Shenzhen Boon Medical Supply Co., Ltd |
| **Regulation Number:** | 21 CFR 870.1650 |
| **Regulation Description:** | Angiographic injector and syringe |
| **Product Code:** | DXT |
| **Device Class:** | Class II |

## 6. Intended Use

The proposed device is intended for the injection of contrast media or saline; it shall be used with US legally marketed angiographic injectors.

## 7. Device description

The proposed device is intended for the injection of contrast media or saline. It includes disposable syringes, spikes, J straws, and tubings. The syringes are intended to be used with a U.S. legally marketed angiography injector. Spikes and J straws are used to draw contrast media/saline into the syringe barrel. Tubings are used to connect the syringe and the catheter.

## 8. Device configurations and compatible injectors

| Model no. | Compatible Device | 510(k) no. |
|---|---|---|
| 900103T, 900103H | Illumena® Néo<br>Angiomat® Illumena® | K963071 |
| 801800H | OptiStar® Elite<br>OptiStar® LE | K073592 |
| 800099T, 800099H,<br>800096T, 800096H | OptiVantage®<br>OptiOne® | K063503,<br>K152361 |
| 844023T, 844023H,<br>844022T, 844022H | OptiVantage® | K063503 |

| Content | Model no. | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **900103T** | **900103H** | **801800H** | **800099T** | **800099H** | **800096T** | **800096H** | **844023T** | **844023H** | **844022T** | **844022H** |
| 150 ml Syringe | 1 | 1 | | | | | | | | | |
| 60 ml Syringe | | | 2 | | | | | | | | |
| 200 ml Syringe | | | | 1 | 1 | 1 | 1 | 2 | 2 | 2 | 2 |
| Small Spike | | | 2 | | | | | | 1 | | 1 |
| Large Spike | | 1 | | | 1 | | 1 | | 1 | | 1 |
| J Straw | 1 | | | 1 | | 1 | | 2 | | 2 | |
| 150 cm Coiled Tubing | | | | 1 | 1 | | | | | | |
| 150 cm Y Coiled Tubing | | | | | | | | | | 1 | 1 |
| 150 cm Y Coiled Tubing with Dual Check Valves | | | | | | | | 1 | 1 | | |
| 230 cm Y Coiled Tubing with Single Check Valve | | | 1 | | | | | | | | |
| Maximum Withstand Pressure | 1200psi | 1200psi | 350psi | 400psi | 400psi | 400psi | 400psi | 400psi | 400psi | 400psi | 400psi |
| Compatible Injector made by Guerbet LLC/ Liebel-Flarsheim LLC | Illumena® Néo / Angiomat® Illumena® | | OptiStar ® Elite / OptiStar ® LE | OptiVantage® / OptiOne® | | | | OptiVantage® | | | |

## 9. Critical syringe dimensions for connection to injectors

- Barrel

| Item | Syringe series | | |
|---|---|---|---|
| | 60mL | 150mL | 200mL |
| Barrel Outer Diameter | Ø29.5 mm | Ø43.8 mm | Ø49.8 mm |
| Barrel Length | 147.0 mm | 217.8 mm | 217.93 mm |
| Barrel Flange Width | 34.55 mm | Not Applicable | Not Applicable |

- Plunger

| Item | Syringe series | | |
|---|---|---|---|
| | 60mL | 150mL | 200mL |
| Plunger/ Plunger Rod Outer Diameter | Ø32 .5 mm | Ø9.6 mm | Ø9.7 mm |
| Plunger Neck Outer Diameter | Not Applicable | Ø4.8 mm | Ø4.85 mm |
| Plunger Rod Depth | Not Applicable | 3.55 mm | 3.56 mm |
| Plunger Length | 148.4 mm | Not Applicable | Not Applicable |

## 10. Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, Disposable Syringes with Accessories for Power Injectors.

➢ **<u>Biocompatibility testing</u>**

The biocompatibility evaluation for the subject device was in accordance with the FDA Biocompatibility guidance (Use of International Standard ISO10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”).

We have executed the following test. Test results meet the acceptance criteria.

- Cytotoxicity Test
- Sensitization Test
- Irritation or Intracutaneous Reactivity Test
- Acute Systemic Toxicity Test
- Material-mediated Pyrogenicity Test
- Hemocompatibility Test
- Particulate Test

- **EO Sterilization validation report**

  A series of tests, including bioburden test, EO and ECH residual test, sterility test has been conducted to validate the EO sterilization of the subject device. Test results showed the validation meet the requirements of ISO 11135 and the achievement of the required sterility assurance level (SAL) of $10^{-6}$.

- **Reliability and performance testing**

  Performance testing per ISO 7886-1:2017 and ISO 80369-7:2021 along with compatibility testing with corresponding injectors are conducted for each configuration. A series of tests was conducted on the subject device after 3 years of accelerated aging to support the shelf life of 3 years. Visual inspection, package bubble test, dye penetration test, and seal strength tests were conducted to validate package integrity. Test results showed the subject device validation meets the requirements of its pre-defined acceptance criteria.

## 11. Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

## 12. Substantial equivalence comparison

Disposable Syringes with Accessories for Power Injectors submitted in 510(k) files is substantially equivalent in intended use, safety and performance to the FDA cleared “Sterile High-pressure Angiographic Syringes for Single-use (K192657)”. Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

| Item | Subject device | Predicate device | Equivalence Discussion |
|---|---|---|---|
| **Proprietary name** | **Disposable Syringe with Accessories for Power Injectors** | **Sterile High-pressure Angiographic Syringes for Single-use** | **-** |
| **510(k) No.** | **K252652** | **K192657** | **-** |
| **Product Code** | DXT | DXT | Same |
| **Regulation No.** | CFR 870.1650 | CFR 870.1650 | Same |
| **Class** | II | II | Same |
| **Intended Use** | The proposed device is intended for the injection of contrast media or saline; it shall be used with US legally | Sterile High-pressure Angiographic Syringes for Single-use are intended for the injection of contrast | Same |

| Item | Subject device | Predicate device | Equivalence Discussion |
|---|---|---|---|
| **Proprietary name** | **Disposable Syringe with Accessories for Power Injectors** | **Sterile High-pressure Angiographic Syringes for Single-use** | **-** |
| **510(k) No.** | **K252652** | **K192657** | **-** |
| | marketed angiographic injectors. | media or saline; they shall be used with an US legally marketed angiographic injectors. | |
| **Mode of Operation** | Power-Driven, single use | Power-Driven, single use | Same |
| **Configuration** | Angiographic Syringe<br>Connection tube<br>J shape tube/ Spike | Angiographic Syringe<br>Connection tube<br>J shape tube/ Spike | Same |
| **Syringe volume (ml)** | Single shot:<br>150, 200<br><br>Dual shot:<br>60/60, 200/200 | Single shot:<br>200, 150, 125, 130, 100,<br><br>Dual shot:<br>200/200, 60/100, 125/125, 100/100, 65/65, 65/115, 60/60,<br>50/50 | Difference #1 |
| **Connection tube length (mm)** | 1500~2500 | 200~2500, 1500~2500, 1500, 1800, 2000, 2500, 500, 750, 1000, 1200 | Difference #1 |
| **Spike length (mm)** | 33, 62 | 58.8, 47.3, 1000, 2800, 1200,<br>2900, 180, 260, 340, 420, 500, | Difference #1 |
| **J shape tube length (mm)** | 250 | 240 | Difference #1 |
| **Pressure Limit (psi)** | 350, 400, 1200 | 400, 1200 | Difference #1 |
| **Performance** | ISO 7886-1, ISO 80369-7 | ISO 7886, ISO 594-1 and ISO 594-2 | Difference #2 |

| Item | | Subject device | Predicate device | Equivalence Discussion |
|---|---|---|---|---|
| **Proprietary name** | | **Disposable Syringe with Accessories for Power Injectors** | **Sterile High-pressure Angiographic Syringes for Single-use** | **-** |
| **510(k) No.** | | **K252652** | **K192657** | **-** |
| **Sterilization** | | EO Sterilized | EO Sterilized | Same |
| **Syringe** | **Barrel** | Polypropylene (PP) or PolyCyclohexylenedimethylene Terephthalate Glycol (PCTG) | PP (polypropylene) or PET (Polyethylene terephthalate) | Difference #3 |
| | **Piston** | Silicone or Isobutylene Isoprene rubber (IIR) | Polyisoprene rubber | Difference #3 |
| | **Lubricant** | Polydimethylsiloxane | Polydimethylsiloxane | Same |
| **Connection tube** | **Tubing** | polyvinyl chloride (PVC) | PVC (Polyvinylchloride with DEHP) or PVC (Polyvinylchloride without DEHP) or PU (Polyurethane) | Difference #3 |
| | **Luer connectors** | Polycarbonate (PC) or polyvinyl chloride (PVC) | Polycarbonate (PC) | Difference #3 |
| | **Ultraviolet adhesive** | Solvent adhesive (Cyclohexanone + Ethyl Acetate) | Ultraviolet adhesive | Difference #3 |
| **Spike** | **Closure-piercing device** | Acrylonitrile-butadiene-styrene (ABS) | Acrylonitrile-butadiene-styrene (ABS) | Same |
| | **Protective cap** | Polypropylene (PP) or polyethylene+ethylene-vinyl acetate (PE+EVA) | Acrylonitrile-butadiene-styrene (ABS) | Difference #3 |
| **J shape tube** | | Polyethylene (PE) | Polyethylene (PE) | Same |
| **Shelf life** | | 3 years | 5 years | Difference #4 |

## 13. Similarity and difference

The subject device, Disposable Syringes with Accessories for Power Injectors, has been compared with the Sterile High-pressure Angiographic Syringes for Single-use (K192657). The subject device has the same intended use, environment of use, user population, interaction with patient / anatomical location of use, sterilization method, design principles as the predicate devices.

The differences between both devices are outlined as below:

Difference #1 - Specification

The specification for volume of syringe, length of connection tube, spike and J shape tube, maximum withstanding pressure are different from the predicate device. Performance tests per ISO 7886-1 and ISO 80369-7, and compatibility testing with corresponding compatible injectors has been conducted. The test results demonstrated that the difference in specifications, maximum withstanding pressure will not cause pressure leakage or adversely affect device performance. Therefore, the difference does not raise different questions of safety and effectiveness of the subject device when compared to the predicate device.

Difference #2 – Conforming ISO standards

ISO 594-1, -2 have been replaced by ISO 80369-7. This does not raise different questions of safety and effectiveness when compared to the predicate device.

Difference #3 - Material

The materials of the syringe, connection tube, and spike of the subject device are different from the material used in the predicate device. Biocompatibility testing of the final finished device demonstrated that the final finished device does not raise any biocompatibility concerns. Therefore, this difference does not raise different questions of safety and effectiveness of the proposed device when compared to the predicate device.

Difference #4 - Shelf Life

The shelf life of the subject device is different from that of the predicate device. However, shelf-life testing was performed on the subject device following accelerated aging, and the test results demonstrated that the subject device maintains its safety and performance throughout the claimed three-year shelf life. Therefore, this difference does not raise different questions of safety and effectiveness of the proposed device when compared to the predicate device.

Based on the above, it has proven the differences between the subject device and the predicate device do not raise any new questions of safety and effectiveness when compared to the predicate device.

## 14. Conclusion

The subject device has been tested for safety and performance, and the test results complied with the test requirements and acceptance criteria of FDA recognized standards. Therefore, the differences between subject device and predicate device do not raise new or different questions of safety or effectiveness. The subject and predicate devices are substantially equivalent.