September 27, 2023

Alton (Shanghai) Medical Instruments Co. Ltd
Wei Song
Project Engineer
No.24 Building Jinshao Rd. 1688.Baoshan District.
Shanghai, 200949
China

Re: K230925
Trade/Device Name: Disposable Injection Needle AF series
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBK
Dated: August 28, 2023
Received: August 28, 2023

Dear Wei Song:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230925

Device Name

Disposable Injection Needle (AF series)

Indications for Use *(Describe)*

The Disposable Injection Needle is intended to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.

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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SECTION 2

510(k) Summary

510(k) Summary

I. SUBMITTER

Name: Alton (Shanghai) Medical Instruments Co. Ltd.

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Date prepared: 2023-09-25

II. Identification of Subjective Device

Device trade name: Disposable Injection Needle

Regulation Name: Endoscope and accessories

Regulation number: 21CFR 876.1500

Regulation class: 2

Review Panel: Gastroenterology/Urology

Product Code Description: Endoscopic Injection Needle, Gastroenterology-Urology

Product code: FBK

III. Identification of Predicate device

Predicate Submission Number: K210917

Trade/Device Name: Single Use Injection Needle

Regulation Name: Endoscope and accessories

Regulation Number: 21 CFR 876.1500

Regulatory Class: 2

Review Panel: Gastroenterology/Urology

Product Code Description: Endoscopic Injection Needle, Gastroenterology-Urology

Product Code: FBK

IV. Device description

The Disposable Injection Needle is a sterile, single-use device as a kind of accessories for digestive endoscopy. The Disposable Injection Needle is intended to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.

The Disposable Injection Needle is designed to insert through the suitable endoscope's forceps to inject harden agent to target lesion in treatment for bleeding of esopha-gastric varix or to mark the lesions of the digestive tract.

The Disposable Injection Needle has different model specifications depending on different working length and the needle size. Details of the models and specifications refer to below table:

No.	Specification No.	Needle Gauge	Needle Length	Outer Tube Diameter	Working length	Min. endoscopic working channel
1	AF-D1818NJ2104	21G	4 mm	Φ1.8 mm	1800 mm	Φ2.0 mm
2	AF-D1818NJ2105		5 mm			
3	AF-D1818NJ2106		6 mm			
4	AF-D1821NJ2104	21G	4 mm	Φ1.8 mm	2100 mm	Φ2.0 mm
5	AF-D1821NJ2105		5 mm			
6	AF-D1821NJ2106		6 mm			
7	AF-D1823NJ2104	21G	4 mm	Φ1.8 mm	2300 mm	Φ2.0 mm
8	AF-D1823NJ2105		5 mm			
9	AF-D1823NJ2106		6 mm			
10	AF-D2418NJ2104	21G	4 mm	Φ2.4 mm	1800 mm	Φ2.8 mm
11	AF-D2418NJ2105		5 mm			
12	AF-D2418NJ2106		6 mm			
13	AF-D2421NJ2104	21G	4 mm	Φ2.4 mm	2100 mm	Φ2.8 mm
14	AF-D2421NJ2105		5 mm			
15	AF-D2421NJ2106		6 mm			
16	AF-D2423NJ2104	21G	4 mm	Φ2.4 mm	2300 mm	Φ2.8 mm
17	AF-D2423NJ2105		5 mm			
18	AF-D2423NJ2106		6 mm			
19	AF-D1818NJ2304	23G	4 mm	Φ1.8 mm	1800 mm	Φ2.0 mm
20	AF-D1818NJ2305		5 mm			
21	AF-D1818NJ2306		6 mm			
22	AF-D1821NJ2304	23G	4 mm	Φ1.8 mm	2100 mm	Φ2.0 mm
23	AF-D1821NJ2305		5 mm			

24	AF-D1821NJ2306		6 mm			
25	AF-D1823NJ2304	23G	4 mm	Φ1.8 mm	2300 mm	Φ2.0 mm
26	AF-D1823NJ2305		5 mm			
27	AF-D1823NJ2306		6 mm			
28	AF-D2418NJ2304	23G	4 mm	Φ2.4 mm	1800 mm	Φ2.8 mm
29	AF-D2418NJ2305		5 mm			
30	AF-D2418NJ2306		6 mm			
31	AF-D2421NJ2304	23G	4 mm	Φ2.4 mm	2100 mm	Φ2.8 mm
32	AF-D2421NJ2305		5 mm			
33	AF-D2421NJ2306		6 mm			
34	AF-D2423NJ2304	23G	4 mm	Φ2.4 mm	2300 mm	Φ2.8 mm
35	AF-D2423NJ2305		5 mm			
36	AF-D2423NJ2306		6 mm			

V. Indication for use

Disposable Injection Needle is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.

VI. Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicative d17evice (K210917)	Discussion/ Conclusion
Manufacturer	Alton (Shanghai) Medical Instruments Co. Ltd	Anrei Medical (Hangzhou) Co., Ltd.	/
Trade name	Disposable Injection Needle	Single Use Injection Needle	/
Regulation name	Endoscope and accessories	Endoscope and accessories	Same
Regulatory Class	II	II	Same
Product code	FBK	FBK	Same
Clinical characteristics			
Indications for use	Disposable Injection Needle is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.	Single use injection needle is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.	Same
General technological characteristics			
Device composition	Needle, bushing, outer tube, infusion inner tube, protective tube, handle and pusher (with Luer connector on top part)	Needle, Connecting Tube, Inner Tube, Sheath, Protect Tube, Metal Tube, handle, Luer Connector	Difference, see Discussion 1
Principle of	The catheter sheath of the product	The catheter sheath of the product	Same

Attribute	Subject device	Predicative d17evice (K210917)	Discussion/ Conclusion
Operation	is inserted into the endoscope channel. When the front part of the catheter sheath is placed on the lesion site, push the Luer connector for injection, the needle is exposed to the catheter sheath, and the needle is inserted into the lesion site, then drug injection.	is inserted into the endoscope channel. When the front part of the catheter sheath is placed on the lesion site, push the Luer connector for injection, the needle is exposed to the catheter sheath, and the needle is inserted into the lesion site, then drug injection.	
Outer Tube diameter	1.8 mm; 2.4 mm	2.4 mm	Difference, see Discussion 2
Minimum endoscopic working channel	Φ2.0 mm; Φ2.8 mm	Φ2.8 mm	Difference, see Discussion 3
Working length	1800 mm; 2100 mm; 2300 mm	1800mm, 2000mm, 2300mm	Same
Needle size	21G; 23G	21G, 23G, 25G	Difference, see Discussion 4
Needle Length	4 mm; 5 mm; 6 mm	4mm, 6mm	Difference, see Discussion 5
Components material	Needle: SUS304 Outer tube: PTFE	Needle: SUS304 Outer tube: PTFE	Same
Sterilization	Method: Ethylene Oxide sterilization SAL: 10^{-6}	Method: Ethylene Oxide sterilization SAL: 10^{-6}	Same
Endotoxin Limit	20EU	20EU	Same
Single use/reuse	For single use	For single use	Same
Shelf life	3 years	3 years	Same
Mechanical performance	Appearance/ Dimension/ Bond Strength/ Operational performance/ Puncture Performance/ Liquid leakage/ Injection connector (Luer connector)/ Patency of lumen/ Corrosion Property	Inserting into endoscope/Withdrawing from endoscope/Advance of tube/Retraction of tube/Smooth puncturing of the needle/Normal reaction force to needle puncturing/Patency of lumen/Needle retraction propriety/Luer lock connector/Dimension	Difference, See Discussion 6
Chemical performance	Appearance (turbidity, color)/pH value/Total dissolved heavy metal	Not publicly available	Difference, See

Attribute	Subject device	Predicative d17evice (K210917)	Discussion/ Conclusion
	content/Potassium permanganate reducing substance/Evaporated residue		Discussion 6
Biocompatibility	Cytotoxicity Skin Sensitization Skin Irritation Test Acute Systemic Toxicity Test, Pyrogen Test Comply with ISO 10993 standards	Cytotoxicity Skin Sensitization Skin Irritation Test Acute Systemic Toxicity Test, Pyrogen Test Comply with ISO 10993 standards	Same

Discussion on differences between the subject device and the predicate device

Discussion 1: Both devices share the same structure except an additional bushing is used in the subjective device to protect the needle, and such difference will not change the intended use and clinical performance of the subjective device. in addition, all mechanical performances an chemical performances between the subject device and the predicate device have been performed to demonstrate substantial equivalence between subject device and predicate device, such difference will not affect the clinical performance and safety of the subjective device.

Discussion 2: There are two specifications (1.8mm; 2.4mm) related to Outer Tube diameter of the needle for the subject device. 2.4mm specification is same as the predicate device. 1.8mm specification is applicable for smaller endoscopic working channel, different from the predicate device. As the size of the outer diameter is designed to be compatible with the smaller size of the endoscopic working channel during the surgical procedure, in addition, the 1.8mm specification has been available on the other marketed device (K212668). Therefore, such differences will not affect clinical performance and safety of the subject device.

Discussion 3: There are two specifications (Φ2.0mm; Φ2.8mm) related to minimum endoscopic working channel for the subject device. Φ2.8mm specification is applicable for types of the subject device with outer tube diameter of the needle (2.4mm) and this Φ2.8mm specification of the subject device is same as the predicate device. Φ2.0mm specification is applicable for types of the subjective device with

smaller outer tube diameter of the needle (1.8mm), different from the predicate device. As the size of the minimum endoscopic working channel is only used to ensure the appropriate size of the injection needle applied during the surgical procedure, and such differences will not affect clinical performance and safety of the subject device.

Discussion 4: there is less optional needle size specifications of the subject device than ones of the predicate device, therefore, such differences will not affect clinical performance and safety of the subject device.

Discussion 5: the needle length specification of the subject device are more than ones of the predicate device, as different needle length is to meet different requirement for different lesion injection or marking, such differences will not affect clinical performance and safety of the subject device.

Discussion 6: The bench performance tests, including mechanical performance and chemical performance, were carried out on both the subject device and the predicate device according to specific product technical specification and the test results demonstrate substantial equivalence between subject device and predicate device. therefore, such difference will not affect effectiveness and safety of the subject device.

VII. Summary of substantial equivalence discussion

Based on the above comparison table as well as discussion on differences, the subject device and the predicate device have similar design features and performance specifications. Although there are some differences on size specification parameters (e.g. outer tube diameter, applicable endoscopic working channel, working length, needle size and needle length) on the subject device and predicate device, such differences will not affect the effectiveness and safety of the subject device. In addition, a performance comparison testing between the subject device and the predicate device is implemented and all performances including mechanical property and chemical property are verified to confirm the performance of the subject device is substantially equivalent to the predicate device. These technological differences between the subject device and the predicate device do not affect the safety and effectiveness of the subject device when used as labeled.

VIII. Summary of Non-clinical Data

Non-clinical testing for Disposable Injection Needle was conducted to verify that the subject device met all design specifications, demonstrated safety and essential performance based on current applicable standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed.

- Biocompatibility

The biocompatibility evaluation for the Disposable Injection Needle was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

- MTT Cytotoxicity Test: ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- Skin Sensitization Test, Skin Irritation Test: ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization
- Acute Systemic Toxicity Test, Subacute Systemic Toxicity Test and Pyrogen Test: ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

- Sterilization Validation

  The EO sterilization of the Disposable Injection Needle has been validated according to the following applicable standards:

  - ISO11135:2014+A1:2018 Sterilization of medical device- validation and routine control of ethylene oxide sterilization
  - ISO 11737-2:2019 Sterilization of Medical Device-Microbiological methods-part 2: Tests of sterility performed in the validation of a sterilization process
  - ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
  - USP <85> Bacterial endotoxins test

- Shelf Life and Sterile Barrier System

Shelf Life and Sterile Barrier System of the Disposable Injection Needle has been validated according to the following applicable standards:

- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO11607-1:2019 Packaging for terminally sterilized Medical Device Part 1: Requirement for materials，sterile barrier systems and packaging systems
- ISO11607-2:2019 Packaging for terminally sterilized Medical Device Part 2: Validation Requirement for forming, sealing and assembly process
- ASTM F 1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D 3078-02(2013): Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- DIN 58593-6: 2016 Sterilization – Sterile Supply – Part 6: Microbial Barrier Testing of Packaging Materials for Medical Devices Which Are to Be Sterilized
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D4169-16 Standard practice for performance testing of shipping containers and systems (DC-13, Level II)

➢ Performance Data – Bench

The performance tests were implemented on both the subject device (Alton Disposable Injection Needle) and the predicate device (Anrei Single Use Injection Needle) to demonstrate substantial equivalence according to the specific product specification with the following test items:

- Appearance
- Dimension
- Bond Strength
- Operational performance
- Puncture Performance
- Liquid leakage

- Injection connector (Luer connector)
- Patency of lumen
- Corrosion Property
- Chemical performance

➢ Performance Data – Animal

N/A, no animal studies are available for the subject device.

IX. Summary of Clinical Data

N/A, no clinical studies are available for the subject device.

X. Conclusions

In conclusion, the technological characteristics, features, specifications, materials, principle of operation, and intended use of the subject device substantially equivalent to the predicate devices quoted above. The differences between the subjective device and its predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that the subject device is substantially equivalent to the legally marketed predicate devices.