May 28, 2021

Anrei Medical (Hangzhou) Co., Ltd.
Huibing Yang
Director, Regulatory Affairs
No.3 Ave.8, HEDA
Hangzhou, Zhejiang 310018
CHINA

Re: K210917
Trade/Device Name: Single Use Injection Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK
Dated: March 25, 2021
Received: March 29, 2021

Dear Huibing Yang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210917

Device Name
Single Use Injection Needle

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Tab #5 510(k) Summary

1. Submitter:

Anrei Medical (Hangzhou) Co., Ltd.
No. 3, Ave 8
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310018 Hangzhou, P.R.China

Contact Person:	Huibing Yang
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Email:	**huibing.yang@anrei.com.cn**
Date Prepared:	3/25/2021

2. Proposed Device:

Trade Name:	Single Use Injection Needle
Regulation Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	FBK
Regulation Class:	II

3. Predicate Device(s):

Primary Predicate Device:

Trade Name:	Injection Needle
510(k) Number:	K150434
Regulation Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	FBK
Regulation Class:	II
Manufacturer:	Micro-Tech (Nanjing) CO., Ltd.

4. Proposed Device Description

The Single Use Injection Needles are sterile, single-use devices. The Single Use Injection Needles can is expected 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 Single Use Injection Needle is designed to pass through the endoscope's forceps to mark the lesions of the digestive tract and use it for injection. Compatibility with endoscopes, working lengths are 1800mm, 2000mm, 2300mm, and the minimum working clamp channel is φ 2.8 mm.

5. Indication for use

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.

6. Technological Characteristics:

The Single use injection needle is available in three needle sizes, two needle size and three working length. The two Characteristics: sizes relate to the needle gauge. The sizes are 21 gauges 23 gauge and 25 gauge. The needle sizes are 4mm, and 6 mm. Working lengths includes 1800mm, 2000mm and 2300mm. There are eighteen (18) models injection needles. Anrei Medical (Hangzhou) believes that the proposed Single use Injection Needle is substantially equivalent to the currently cleared Injection Needle (K150434) in device function and overall design.

7. Summary of non-clinical testing:

Performance testing was conducted to demonstrate the essential performance of the proposed device and confirmed that the proposed device works as intended with the compatible devices. Additionally, the results of the tests below were evaluated as substantially equivalent to the cited predicate devices.

● The following bench testing were performed on the proposed Single Use Injection Needle .

- 1. Inserting into endoscope
- 2. Withdrawing from endoscope
- 3. Advance of tube
- 4. Retraction of tube
- 5. Smooth puncturing of the needle
- 6. Normal reaction force to needle puncturing.
- 7. Patency of lumen
- 8. Needle retraction propriety
- 9. Luer lock connector
- 10. Dimension

● Shelf-Life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. Three-year aging will be performed to demonstrate longer stability and support the results of the accelerated aging test.

● Sterilization validation was conducted in accordance with ISO 11135:2014 using the overkill validation methods to demonstrate the ability to achieve a

sterility assurance level of less than 10^{-6}.

● Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process"

The following standards have been applied to the proposed Single Use Injection Needle .

- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-7:2008 Biological evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ANSI/AAMI/ISO11135:2014 Sterilization of health-care products - Ethylene oxide – Requirement for the development, validation and routine control of a sterilization process for medical devices
- ASTM F88/F88M-15 standard method for seal strength of flexible barrier materials
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	**Proposed Device**	**Predicate Device K150434**	**Substantial Equivalence**
Device name	Single Use Injection Needle	Injection Needle	Predicate Device is single used，Same
Product Code	FBK	FBK	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
User qualification	This device must be used by trained doctors or technicians.	This device must be used by trained doctors or technicians.	Same
Class	II	II	Same
Supplied Sterile	Yes	Yes	Same
Configuration	Needle, Connecting Tube, Inner Tube, Sheath, Protect Tube, Metal Tube, handle, Luer Connector	Needle, inner sheath, outer shell, outer sheath and luer lock	Similar, Tests including biocompatibility, bench performance were performed. The results show the device is substantially equivalent to the currently marketed Micro-Tech (Nanjing) predicate devices.

Outer Sheath diameter	2.4mm	2.3 mm	Similar, the slight difference does not affect the device compatibility with the endoscope of the minimum working cannel size of 2.8 mm.
Working length	1800mm, 2000mm, 2300mm	1800mm, 2000mm, 2300mm	Same
Needle size	21G, 23G, 25G	19G, 22G, 25G	Similar, Within the range of the predicate Needle size.
Needle Length	4mm, 6mm	4mm, 5mm, 6mm	Similar, Within the range of the predicate Needle Length.
Minimum required working channel	φ2.8mm	φ2.8mm	Same
Indication for Use	The 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.	The injection needle is to be used in conjunction with an endoscope to perform endoscopic injections treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.	Same
Single Use	Single Use	Single Use	Same
Labeling	Comply with 21 CFR Part 801	Comply with 21 CFR Part 801	Same
Cytotoxicity	No cytotoxicity	Comply with ISO 10993 standards	Same
Skin Sensitization	No skin sensitization		Same
Irritation	No irritation		Same
Acute Systemic	No acute toxicity		Same

Toxicity			
Pyrogen	No pyrogen		Same
Method	Ethylene oxide	Ethylene oxide	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU	20EU	Same
Shelf life	3 years	3 years	Same

10. Conclusion:

Anrei Medical (Hangzhou) Co., Ltd has demonstrated that the proposed Single Use Injection Needle is substantially equivalent to the currently marketed Micro-Tech (Nanjing) predicate devices and can be safely and effectively used for its proposed indications.