April 12, 2024

Ningbo Xinwell Medical Technology Co., Ltd
Lei Xi
Registration Manager
No.188 Binjiang Road, Cixi High-tech
Industrial Development Zone
Cixi, Zhejiang 315301
China

Re: K232200
Trade/Device Name: Disposable Injection Needles
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK
Dated: March 12, 2024
Received: March 12, 2024

Dear Lei Xi:

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,

Sivakami Venkatachalam -S

for
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)*

K232200

Device Name

Disposable Injection Needles

Indications for Use *(Describe)*

The device is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection 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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1. **SUBMITTER**

Ningbo Xinwell Medical Technology Co., LTD

No.188 Binjiang Road, Cixi High-tech industrial Development Zone, Cixi City, 315301 Zhejiang,P.R.China

Contact Person: Lei Xi

Title: RA manager

Tel: +86574-63026388

Email: xilei@xinhaigroup.com

Summary Prepared: 2024-04-04

2. DEVICE

Name of device: Disposable Injection Needles

Regulation Number: 21 CFR 876.1500

Classification name: Endoscope and accessories

Common name:Endoscopic injection needle

Regulatory Class: Class II

Product Code: FBK

3. PREDICATE DEVICE

The predicate device is Injection Needle(K213914).

4. DEVICE DESCRIPTION

The device is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection in the GI tract.The Disposable Injection Needles are consist of needle tube, inner tube, outer tube, protective sleeve, booster tube, handle, limitation ring, buckle and conical connector. The needle tube and booster tube are made of 06Cr19Ni10. The inner tube and outer tube are made of PP.The handle, limitation ring, buckle and conical connector are made of ABS. The diameter of the outer tube is available in two specifications, respectively are 1.8mm and 2.3mm. There are five specifications for the working length of the outer tube, respectively are 1200mm,1600mm,1800mm,2000mm and 2300mm. There are three specifications for outer diameters of needle tube, respectively are 21G, 23G and 25G. Five specifications for lengths of needle tube, respectively are 4mm, 5mm, 6mm, 7mm and 8mm.

The device is sterilized by ethylene oxide. The shelf life is 3 years.

The inner, middle and transportation packaging ways respectively are sealed pouch, box and carton.The corresponding product quantities is 1 pc per bag, 10 pcs per box and 5 boxes per carton.

5. PRINCIPLE OF OPERATION

The Disposable Injection Needles achieve its intended use by combining them with the flexible channel of the endoscope. Firstly, the Disposable Injection Needles passed through the endoscopic channel to the channel port, and the lesion was determined through the endoscopic visual field. After the lesion was determined, the needle tube of the Disposable Injection Needles was extended out of the outer tube by pushing the conical connector at the end of the handle, and then inserted into the target tissue. And the Luer interface at the end of the handle is connected to the syringe for fluid injection; After the injection is completed, pull the conical connector at the end of the handle to retrieve the needle tube into the outer tube, and then withdraw the Disposable Injection Needles from the endoscopic channel.

6. Available model

Specification and Model	Model Code	Outer tube diameter (mm)	Working length (mm)	Outer diameter of needle tube (G)	Length of needle tube (mm)
XY-ZSZ-C-18×1200×21×4	C	1.8	1200	21	4
XY-ZSZ-C-18×1200×21×5	C	1.8	1200	21	5
XY-ZSZ-C-18×1200×21×6	C	1.8	1200	21	6
XY-ZSZ-C-18×1200×21×7	C	1.8	1200	21	7
XY-ZSZ-C-18×1200×21×8	C	1.8	1200	21	8
XY-ZSZ-C-18×1200×23×4	C	1.8	1200	23	4
XY-ZSZ-C-18×1200×23×5	C	1.8	1200	23	5
XY-ZSZ-C-18×1200×23×6	C	1.8	1200	23	6
XY-ZSZ-C-18×1200×23×7	C	1.8	1200	23	7
XY-ZSZ-C-18×1200×23×8	C	1.8	1200	23	8
XY-ZSZ-C-18×1200×25×4	C	1.8	1200	25	4
XY-ZSZ-C-18×1200×25×5	C	1.8	1200	25	5
XY-ZSZ-C-18×1200×25×6	C	1.8	1200	25	6
XY-ZSZ-C-18×1200×25×7	C	1.8	1200	25	7
XY-ZSZ-C-18×1200×25×8	C	1.8	1200	25	8
XY-ZSZ-C-18×1600×21×4	C	1.8	1600	21	4
XY-ZSZ-C-18×1600×21×5	C	1.8	1600	21	5
XY-ZSZ-C-18×1600×21×6	C	1.8	1600	21	6
XY-ZSZ-C-18×1600×21×7	C	1.8	1600	21	7
XY-ZSZ-C-18×1600×21×8	C	1.8	1600	21	8
XY-ZSZ-C-18×1600×23×4	C	1.8	1600	23	4
XY-ZSZ-C-18×1600×23×5	C	1.8	1600	23	5
XY-ZSZ-C-18×1600×23×6	C	1.8	1600	23	6
XY-ZSZ-C-18×1600×23×7	C	1.8	1600	23	7
XY-ZSZ-C-18×1600×23×8	C	1.8	1600	23	8

XY-ZSZ-C-18×1600×25×4	C	1.8	1600	25	4
XY-ZSZ-C-18×1600×25×5	C	1.8	1600	25	5
XY-ZSZ-C-18×1600×25×6	C	1.8	1600	25	6
XY-ZSZ-C-18×1600×25×7	C	1.8	1600	25	7
XY-ZSZ-C-18×1600×25×8	C	1.8	1600	25	8
XY-ZSZ-C-18×1800×21×4	C	1.8	1800	21	4
XY-ZSZ-C-18×1800×21×5	C	1.8	1800	21	5
XY-ZSZ-C-18×1800×21×6	C	1.8	1800	21	6
XY-ZSZ-C-18×1800×21×7	C	1.8	1800	21	7
XY-ZSZ-C-18×1800×21×8	C	1.8	1800	21	8
XY-ZSZ-C-18×1800×23×4	C	1.8	1800	23	4
XY-ZSZ-C-18×1800×23×5	C	1.8	1800	23	5
XY-ZSZ-C-18×1800×23×6	C	1.8	1800	23	6
XY-ZSZ-C-18×1800×23×7	C	1.8	1800	23	7
XY-ZSZ-C-18×1800×23×8	C	1.8	1800	23	8
XY-ZSZ-C-18×1800×25×4	C	1.8	1800	25	4
XY-ZSZ-C-18×1800×25×5	C	1.8	1800	25	5
XY-ZSZ-C-18×1800×25×6	C	1.8	1800	25	6
XY-ZSZ-C-18×1800×25×7	C	1.8	1800	25	7
XY-ZSZ-C-18×1800×25×8	C	1.8	1800	25	8
XY-ZSZ-C-18×2000×21×4	C	1.8	2000	21	4
XY-ZSZ-C-18×2000×21×5	C	1.8	2000	21	5
XY-ZSZ-C-18×2000×21×6	C	1.8	2000	21	6
XY-ZSZ-C-18×2000×21×7	C	1.8	2000	21	7
XY-ZSZ-C-18×2000×21×8	C	1.8	2000	21	8
XY-ZSZ-C-18×2000×23×4	C	1.8	2000	23	4
XY-ZSZ-C-18×2000×23×5	C	1.8	2000	23	5
XY-ZSZ-C-18×2000×23×6	C	1.8	2000	23	6
XY-ZSZ-C-18×2000×23×7	C	1.8	2000	23	7
XY-ZSZ-C-18×2000×23×8	C	1.8	2000	23	8
XY-ZSZ-C-18×2000×25×4	C	1.8	2000	25	4
XY-ZSZ-C-18×2000×25×5	C	1.8	2000	25	5
XY-ZSZ-C-18×2000×25×6	C	1.8	2000	25	6
XY-ZSZ-C-18×2000×25×7	C	1.8	2000	25	7
XY-ZSZ-C-18×2000×25×8	C	1.8	2000	25	8
XY-ZSZ-C-18×2300×21×4	C	1.8	2300	21	4
XY-ZSZ-C-18×2300×21×5	C	1.8	2300	21	5

XY-ZSZ-C-18×2300×21×6	C	1.8	2300	21	6
XY-ZSZ-C-18×2300×21×7	C	1.8	2300	21	7
XY-ZSZ-C-18×2300×21×8	C	1.8	2300	21	8
XY-ZSZ-C-18×2300×23×4	C	1.8	2300	23	4
XY-ZSZ-C-18×2300×23×5	C	1.8	2300	23	5
XY-ZSZ-C-18×2300×23×6	C	1.8	2300	23	6
XY-ZSZ-C-18×2300×23×7	C	1.8	2300	23	7
XY-ZSZ-C-18×2300×23×8	C	1.8	2300	23	8
XY-ZSZ-C-18×2300×25×4	C	1.8	2300	25	4
XY-ZSZ-C-18×2300×25×5	C	1.8	2300	25	5
XY-ZSZ-C-18×2300×25×6	C	1.8	2300	25	6
XY-ZSZ-C-18×2300×25×7	C	1.8	2300	25	7
XY-ZSZ-C-18×2300×25×8	C	1.8	2300	25	8
XY-ZSZ-C-23×1200×21×4	C	2.3	1200	21	4
XY-ZSZ-C-23×1200×21×5	C	2.3	1200	21	5
XY-ZSZ-C-23×1200×21×6	C	2.3	1200	21	6
XY-ZSZ-C-23×1200×21×7	C	2.3	1200	21	7
XY-ZSZ-C-23×1200×21×8	C	2.3	1200	21	8
XY-ZSZ-C-23×1200×23×4	C	2.3	1200	23	4
XY-ZSZ-C-23×1200×23×5	C	2.3	1200	23	5
XY-ZSZ-C-23×1200×23×6	C	2.3	1200	23	6
XY-ZSZ-C-23×1200×23×7	C	2.3	1200	23	7
XY-ZSZ-C-23×1200×23×8	C	2.3	1200	23	8
XY-ZSZ-C-23×1200×25×4	C	2.3	1200	25	4
XY-ZSZ-C-23×1200×25×5	C	2.3	1200	25	5
XY-ZSZ-C-23×1200×25×6	C	2.3	1200	25	6
XY-ZSZ-C-23×1200×25×7	C	2.3	1200	25	7
XY-ZSZ-C-23×1200×25×8	C	2.3	1200	25	8
XY-ZSZ-C-23×1600×21×4	C	2.3	1600	21	4
XY-ZSZ-C-23×1600×21×5	C	2.3	1600	21	5
XY-ZSZ-C-23×1600×21×6	C	2.3	1600	21	6
XY-ZSZ-C-23×1600×21×7	C	2.3	1600	21	7
XY-ZSZ-C-23×1600×21×8	C	2.3	1600	21	8
XY-ZSZ-C-23×1600×23×4	C	2.3	1600	23	4
XY-ZSZ-C-23×1600×23×5	C	2.3	1600	23	5
XY-ZSZ-C-23×1600×23×6	C	2.3	1600	23	6
XY-ZSZ-C-23×1600×23×7	C	2.3	1600	23	7

XY-ZSZ-C-23×1600×23×8	C	2.3	1600	23	8
XY-ZSZ-C-23×1600×25×4	C	2.3	1600	25	4
XY-ZSZ-C-23×1600×25×5	C	2.3	1600	25	5
XY-ZSZ-C-23×1600×25×6	C	2.3	1600	25	6
XY-ZSZ-C-23×1600×25×7	C	2.3	1600	25	7
XY-ZSZ-C-23×1600×25×8	C	2.3	1600	25	8
XY-ZSZ-C-23×1800×21×4	C	2.3	1800	21	4
XY-ZSZ-C-23×1800×21×5	C	2.3	1800	21	5
XY-ZSZ-C-23×1800×21×6	C	2.3	1800	21	6
XY-ZSZ-C-23×1800×21×7	C	2.3	1800	21	7
XY-ZSZ-C-23×1800×21×8	C	2.3	1800	21	8
XY-ZSZ-C-23×1800×23×4	C	2.3	1800	23	4
XY-ZSZ-C-23×1800×23×5	C	2.3	1800	23	5
XY-ZSZ-C-23×1800×23×6	C	2.3	1800	23	6
XY-ZSZ-C-23×1800×23×7	C	2.3	1800	23	7
XY-ZSZ-C-23×1800×23×8	C	2.3	1800	23	8
XY-ZSZ-C-23×1800×25×4	C	2.3	1800	25	4
XY-ZSZ-C-23×1800×25×5	C	2.3	1800	25	5
XY-ZSZ-C-23×1800×25×6	C	2.3	1800	25	6
XY-ZSZ-C-23×1800×25×7	C	2.3	1800	25	7
XY-ZSZ-C-23×1800×25×8	C	2.3	1800	25	8
XY-ZSZ-C-23×2000×21×4	C	2.3	2000	21	4
XY-ZSZ-C-23×2000×21×5	C	2.3	2000	21	5
XY-ZSZ-C-23×2000×21×6	C	2.3	2000	21	6
XY-ZSZ-C-23×2000×21×7	C	2.3	2000	21	7
XY-ZSZ-C-23×2000×21×8	C	2.3	2000	21	8
XY-ZSZ-C-23×2000×23×4	C	2.3	2000	23	4
XY-ZSZ-C-23×2000×23×5	C	2.3	2000	23	5
XY-ZSZ-C-23×2000×23×6	C	2.3	2000	23	6
XY-ZSZ-C-23×2000×23×7	C	2.3	2000	23	7
XY-ZSZ-C-23×2000×23×8	C	2.3	2000	23	8
XY-ZSZ-C-23×2000×25×4	C	2.3	2000	25	4
XY-ZSZ-C-23×2000×25×5	C	2.3	2000	25	5
XY-ZSZ-C-23×2000×25×6	C	2.3	2000	25	6
XY-ZSZ-C-23×2000×25×7	C	2.3	2000	25	7
XY-ZSZ-C-23×2000×25×8	C	2.3	2000	25	8
XY-ZSZ-C-23×2300×21×4	C	2.3	2300	21	4

XY-ZSZ-C-23×2300×21×5	C	2.3	2300	21	5
XY-ZSZ-C-23×2300×21×6	C	2.3	2300	21	6
XY-ZSZ-C-23×2300×21×7	C	2.3	2300	21	7
XY-ZSZ-C-23×2300×21×8	C	2.3	2300	21	8
XY-ZSZ-C-23×2300×23×4	C	2.3	2300	23	4
XY-ZSZ-C-23×2300×23×5	C	2.3	2300	23	5
XY-ZSZ-C-23×2300×23×6	C	2.3	2300	23	6
XY-ZSZ-C-23×2300×23×7	C	2.3	2300	23	7
XY-ZSZ-C-23×2300×23×8	C	2.3	2300	23	8
XY-ZSZ-C-23×2300×25×4	C	2.3	2300	25	4
XY-ZSZ-C-23×2300×25×5	C	2.3	2300	25	5
XY-ZSZ-C-23×2300×25×6	C	2.3	2300	25	6
XY-ZSZ-C-23×2300×25×7	C	2.3	2300	25	7
XY-ZSZ-C-23×2300×25×8	C	2.3	2300	25	8

7. Indication for use

The device is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection in the GI tract.

8. Comparison of technological characteristics with the predicate device

The Disposable Injection Needles are compared with the predicate device Injection Needles(K213914).The results are shown below in the Technological Characteristics Comparison Table:

ITEM	Proposed Device	Predicate Device K213914	Remark
Product	Disposable Injection Needles	Injection Needle	/
Product Code	FBK	FBK	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Class	Class II	Class II	Same
Indication for Use	The device is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection in the GI tract.	The device is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection in the GI tract.	Same

Configuration	Needle tube, Inner tube, Outer tube, Protective sleeve, Handle, Limitation ring, Buckle, Conical connector, Booster tube.	needle, connector tube, guiding head, inner tube, outer tube, protective sleeve, front handle, injection handle, front handle cover, boosting tube.	Difference
Environment of use	Hospital	Hospital	Same
Intended users	The device must be used by trained doctors or technicians.	The device must be used by trained doctors or technicians.	Same
Single Use	Single Use	Single Use	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Specifications			
Working Length	1200mm,1600mm, 1800mm,2000mm 2300mm	1200mm, 1800mm, 2300mm, 3000mm	Difference
Minimum working channel	2.0mm, 2.8mm	2.0mm, 2.8mm	Same
Needle Size	21G, 23G, 25G	19G, 20G, 21G, 22G, 23G, 25G	Difference
Needle Length	4mm, 5mm, 6mm, 7mm,	3mm, 4mm, 5mm, 6mm, 8mm	Difference
Patient contact material	Needle tube :Stainless steel（06Cr19Ni10） Inner tube :PP Outer tube:PP Booster tube:Stainless steel（06Cr19Ni10） Conical connector:ABS	Needle: S30400 Guiding Head: S30300 Inner Tube: PTFE or PP Outer Tube: PTFE or PP Injection Handle: ABS Boosting Tube: S30400	Difference
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	Same
Sensitization	No skin sensitization	No skin sensitization	Same
Systemic Toxicity	No systemic toxicity	No systemic toxicity	Same
Pyrogen	No Pyrogen	No Pyrogen	Same

Hemolysis Properties	No Hemolysis	No Hemolysis	Same
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

9. Performance data

Non-clinical performance test conclusion

Biocompatibility

Biocompatibility testing was performed on the proposed device in accordance with the following standards:

ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

ISO 10993-4:2017 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood

ISO 10993-10:2021 Biological evaluation of medical devices — Part 10: Tests for skin sensitization

ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation

ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials

ASTM F2382-18 Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)

ASTM F2888-19 Standard Practice for Platelet Leukocyte Count—An In-Vitro Measure for Hemocompatibility Assessment of Cardiovascular Materials

Performance bench testing

The basic safety and essential performance comparison test were evaluated based on as following standards:

ISO 20695:2020 Enteral feeding systems-Design and testing (tensile strength, fracture force).

ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices-Requirements and test methods.

ISO 13402:1995 Surgical and dental hand instruments-Determination of resistance against autoclaving, corrosion and thermal exposure.

ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for intravascular or hypodermic applications.

ISO 7864:2016 Sterile hypodermic needles for single use-Requirements and test methods

Testing for patency, injection residue and needle retraction suitability was performed.

Clinical test conclusion

No clinical study is included in this submission.

10. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device Injection Needle (K213914).