DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 2, 2015

Micro-Tech (Nanjing) CO., Ltd.
Becky Li
Manager of Quality Department
No. 10, Gaoke Third Road
High-New Tech Industry Development Dist.
Nanjing, Jiangsu, 210032
China

Re: K150434
Trade/Device Name: Injection Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK
Dated: April 14, 2015
Received: April 20, 2015

Dear Becky Li,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150434

Device Name
Injection Needle

Indications for Use *(Describe)*
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.

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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Tab7

510K Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. **Date of Preparation: 01/16/2015**

2. **Sponsor Identification**

   Micro-Tech (Nanjing) Co., Ltd.
   No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC
   Establishment Registration Number: 3004837686
   Contact Person: Becky Li
   Position: Manager of Quality Department
   Tel: +86-25-58646378
   Fax: +86-25-58744269
   Email: In@micro-tech.com.cn

3. **Identification of Proposed Device**

   Product Name: Injection Needle
   Common Name: Endoscopic Needle
   Regulatory Information
   Classification Name: Endoscopy and accessories
   Classification: 2
   Product Code: FBK
   Regulation Number: 876.1500
   Review Panel: Gastroenterology/Urology

4. **Indications 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.

5. Device Description

The injection needle consists of a stainless steel needle attached to plastic tubing and luer lock hub where a standard syringe can be attached for injection of materials through the lumen of the needle into tissue. The minimum required working channel for this proposed product is 2.8mm.

The proposed products are intended for single use, an individual device is packed in a sealed pouch following ETO sterilization. The device is used for local injection via endoscope, with the average contact time of the product and the mucosa of the human digestive tract of less than 1 hour.

6. Identification of Predicate Device

510(k) Number: K061222

Product Name: *Injectra* Injection Needle

7. Technological Characteristics:

The injection needle is available in three needle sizes, three needle size and three working length. The two Characteristics: sizes relate to the needle gauge. The sizes are 19 gauges 22 gauge and 25 gauge. The needle sizes are 4mm, 5mm and 6 mm. Working lengths includes 1800mm, 2000mm and 2300mm. There are twenty-seven (27) models injection needles. Micro-Tech (Nanjing) believes that the proposed Injection Needle is substantially equivalent to the currently cleared ***Injectra*** Injection Needle (K061222) in device function and overall design.

8. Testing Performed:

Biocompatibility, accelerated aging, performance, and sterilization validation testing was performed on the injection needle that demonstrated that this device is safe and effective for use. Testing was based on a formal risk analysis.

The following table shows a summary substantial equivalence of the Injection Needle and the chosen predicate, indicating no additional safety risks arise in the new device based on similarities in materials, intended use, and function of the Injection Needle in comparison to the predicate device.

Table 1 Comparison of Technology Characteristics

Item	Proposed Device Injection Needle	Predicate Device 2 ***Injectra*** Injection Needle (K061222)	Substantial Equivalence
Product Code	FBK	FBK	Same
Regulation No.	876.1500	876.1500	Same
Class	2	2	Same
Supplied Sterile	Yes	Yes	Same
Outer Sheath diameter	2.3 mm	2.3 mm	Same
Needle size	19gauge, 22gauge, 25 gauge	19gauge, 22gauge, 25 gauge	Same
Outer Sheath Material	Thermoplastic-PTFE Polymer	Thermoplastic-PTFE Polymer	Same
Working Length	1800mm, 2000mm, 2300mm	1200mm,1600mm,1800mm, 2300mm	Similar
Needle Length	4mm, 5mm, 6mm	4mm,6mm	Similar
Indications 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	The ***Injectra*** Injection Needle is a complete one-piece injection needle intended for	Similar

Item	Proposed Device Injection Needle	Predicate Device 2 ***Injectra*** Injection Needle (K061222)	Substantial Equivalence
	and gastric varies and for submucosal dye marking in the GI tract.	endoscopic injection of solutions such as sclerosing agents into tissues of the digestive system to control bleeding and for injection of saline as a procedural aid in endoscopic Polypectomy procedures. The Injectra Injection Needle is a disposable device and is intended for single patient use only.	
Configuration	Needle, inner sheath, outer shell, outer sheath and luer lock	Needle, inner sheath, outer shell, outer sheath and luer lock	Similar
Single Use	Yes	Yes	Same

Item	Proposed Device Injection Needle	Predicate Device 2 ***Injectra*** Injection Needle (K061222)	Substantial Equivalence
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Similar

9. Substantially Equivalent (SE) Conclusion

Based on the technological characteristics and overall performance of the devices, Micro-Tech (Nanjing) CO., Ltd. believes that the Injection Needle and the predicate device selected are substantially equivalent. While the intended uses are slightly different, both devices are intended to be used in the same body regions during endoscopic procedures for injection of fluids. Therefore, this difference is minor, and does not raise new issues of safety or effectiveness.