DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 15, 2015

Wilson Instruments (Shanghai) Company Limited
Lijuan Zhang
Regulatory Manager
Building 5, No. 258 Shuangbang Road
Xujing Town, Qingpu District, Shanghai, 201702
China

Re: K142144
Trade/Device Name: Disposable Injection Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK
Dated: December 9, 2014
Received: December 10, 2014

Dear Lijuan Zhang,

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,

Joyce M. Whang -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)*
K142144

Device Name
Disposable Injection Needle (PN series, PM series, PM (H) series)

Indications for Use *(Describe)*
Wilson disposable injection needle has been designed to be used with an endoscope to perform following therapy:
1. Endoscopic sclerotherapy within the esophagus, stomach, duodenum, small intestine, large intestine.
2. Endoscopic hemostasis within the esophagus, stomach, duodenum, small intestine, large intestine.
3. Endoscopic submucosal injection within esophagus, stomach, duodenum, small intestine, large intestine.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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007_510(k) Summary

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

Nov 28th, 2014

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor:	Wilson Instruments (Shanghai) Company Limited
Address:	Building 5, No.258 Shuangbang Road, Xujing Town Qingpu District Shanghai China
Contact Name:	Lijuan Zhang
Telephone No.:	+86 (021) 39290005
Fax No.:	+86 (021) 66311471
Email Address:	wilson.ljzhang@gmail.com

3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name:	Disposable Injection Needle
Model Name:	PN series, PM series, PM(H) series
Common Name:	Endoscopic Injection Needle
Regulatory Classification:	21 CFR 876.1500 Endoscope and accessories
Product Code:	FBK
Classification Panel:	Gastroenterology/Urology
Device Class:	II

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicates within this submission are as follows:
Olympus Optical Co., Ltd., Olympus Injector NM-4-1, NM-5-1, NM-6-1, NM-7-1, NM-8-1, NM-7-1, NM-8-1, NM-9-1 has been cleared by FDA through 510(k) No. K011484 (Decision Date – Aug 10, 2001).

5. Description of the Device [21 CFR 807.92(a)(4)]

The subjected Disposable Injection Needle is operated together with an endoscope to conduct an endoscopic injection for the treatment of esophageal and gastric varices and submucosal injection in the digestive tract, such as esophagus, stomach, duodenum, small intestine, large intestine.
The subjected device is primarily constituted of handle, tube and needle. The models include PN series, PM series and PM(H) series.

6. Intended Use [21 CFR 807.92(a)(5)]

Wilson disposable injection needle has been designed to be used with an endoscope to perform following therapy:
1. Endoscopic sclerotherapy within the esophagus, stomach, duodenum, small intestine, large intestine.
2. Endoscopic hemostasis within the esophagus, stomach, duodenum, small intestine, large intestine.
3. Endoscopic submucosal injection within esophagus, stomach, duodenum, small intestine, large intestine.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

As the reason that the working situation and environment of Wilson's Disposable Injection Needle is the same as that of the similar Olympus Injector, the technological characteristics of this product series are designed to make same as that of the equivalence product, including product structure such as the scope of working length for the product series, the maximum insertion portion diameter, the minimum endoscope working channel size, etc., and such as the application of materials over different parts of the product series are also be designed to be equal respectively. It applies EO sterilization method, which is also same as that of predicate device.

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

The disposable injection needle of Wilson has taken the biocompatibility, sterility and performance testing into concern in accordance with Food and Drug Administration related guidance and recognized international standards. Test data and report information included in this submission demonstrate that the subjected device is substantially equivalent to the predicate device.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Wilson Instruments (Shanghai) Company Limited concludes that Disposable Injection Needle is substantially equivalent to predicate devices with regard to safety and effectiveness.