December 21, 2018

Finemedix Co. Ltd.
% April Lee
Consultant
Withus Group Inc.
106 Superior
Irvine, CA 92620

Re: K181690
Trade/Device Name: Clear-Jet Injection Catheter
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK
Dated: November 13, 2018
Received: November 20, 2018

Dear April Lee:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -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)*
K181690

Device Name
Clear-Jet Injection Catheter

Indications for Use *(Describe)*
The Clear-Jet Injection Catheter is to be used in conjunction with an endoscope to perform endoscopic injections, such as 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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510(k) Summary

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Device Information

- Trade Name: Clear-Jet Injection Catheter
- Common Name: Endoscopic Injection Needle
- Classification Name: Endoscopic injection needle, gastroenterology-urology
- Product Code: FBK
- Panel: Gastroenterology/Urology
- Regulation Number: 21 CFR 876.1500 Endoscope and Accessories
- Device Class: Class II
- Date Prepared: 06/20/2018

Predicate Devices:
The subject device is substantially equivalent to the following predicate devices:

- K150434, Injection Needle manufactured by Micro-Tech (Nanjing) Co., Ltd.

Indication for Use:
The Clear-Jet Injection Catheter is to be used in conjunction with an endoscope to perform endoscopic injections, such as the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.

Device Description:
Clear-Jet Injection Catheter consists of a stainless-steel needle attached to inner tube, an Injector Head attached to Catheter tube, and Slider where a standard syringe can be attached for injection of solutions through the lumen of the needle into tissue. It is available in various sizes and working lengths. The needle sizes are 21 gauge (outer diameter 0.8mm) and 23 gauge (outer diameter 0.6mm), and the needle lengths are 4.0mm and 6.0mm. The needle wall thicknesses are 0.1mm, 0.05mm, and 0.08mm, and the Catheter Tube length (=Working length) includes 1,800mm, 2,300mm.

There are two types of Clear-Jet Injection Catheter such as Head type and Non-head type. Head type has the Injector Head made of stainless steel alloys attached to the distal of the Catheter Tube, Non -head type does not have the Injector Head made of stainless steel alloys.

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This device passes through the working channel of endoscope, and the average contact time with mucosa of the human digestive tract is less than 1 hour. This device is supplied sterile for single-patient use and shall be not reused or re-sterilized.

Summary of Technological Characteristics:

		Subject Device	**Primary Predicate**	**Substantial Equivalence**
Company		Finemedix Co., Ltd.	Micro-Tech Co., Ltd.	-
Device Name		Clear-Jet Injection Catheter	Injection Needle	-
510(k) Number		NA	K150434	-
Device Classification Name		Endoscopic injection needle, gastroenterology-urology	Endoscopic injection needle, gastroenterology-urology	Same
Product Code		FBK	FBK	Same
Regulation Number		876.1500	876.1500	Same
Indications for Use		The Clear-Jet Injection Catheter is to be used in conjunction with an endoscope to perform endoscopic injections, such as 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, such as the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.	Same
Material	Needle	Stainless-Steel	Stainless-Steel	Same
	Tube	Thermoplastic-PTFE Polymer	Thermoplastic-PTFE Polymer	Same
Components		Needle, Inner Tube, Catheter Tube, Handle, Slider	Needle, Innersheath, outer shell, outer sheath and luer	Similar
Gauge size		21,23 Gauge	19,22,25 Gauge	Within the range
Supplied Sterile		Yes	Yes	Same

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Outer Sheath Diameter	2.35mm	2.3mm	Similar
Working Length	1800, 2300 mm	1800, 2000, 2300 mm	Within the range
Needle Length	4, 6 mm	4,5,6 mm	Within the range
Packaging	Single-use EO Sterilized Pouch with one device per pouch	Single-use EO Sterilized Pouch with one device per pouch	Same
Single Use	Yes	Yes	Same
Similarities	Both subject and predicate device are substantially equivalent in the indications for use, Material, Components, Design, sterility, outer sheath diameter, working length, needle length, and packaging as charted.		
Differences	The differences between the subject and predicate devices are gauge size and outer sheath diameter. The subject device has 21 and 23 gauge and the predicate device has 19,22,25 gauge. But the subject device gauges are contained within the range of the predicate's gauges, so it does not affect the safety and effectiveness. The other difference is outer sheath diameter. The outer sheath diameter of the subject device is 2.35mm and the outer sheath diameter of the predicate device is 2.3mm. But this size difference doesn't affect the safety and effectiveness during surgery. Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.		

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Non-clinical testing data:

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Biocompatibility testing according to ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010 and ISO 10993-11:2006
- Performance testing such as appearance and dimension
- Physical and Chemical Safety Testing such as color and transparent, pH, KMnO4 Consumption, Non-Volatile residue, ultraviolet absorption, heavy metal as lead, EO Sterilization residuals test, and sterility test
- EO Sterilization Testing according to ISO 11737-1:2006 and ISO 11737-2:2009
- Shelf Life Testing according to ASTM F1980

The biocompatibility evaluation for Clear-Jet Injection Catheter was conducted in accordance with *ISO 10993-1*: *2009 "Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing within a Risk Management Process"* and FDA's biocompatibility guidance, *G95-1 Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" (May 1, 1995).* The following tests were completed: Cytotoxicity, Sensitization, Intracutaneous reactivity and Acute Systemic Toxicity.

Performance testing such as appearance and dimension and extractable testing such as color and transparent, pH, KMnO4 Consumption, Non-Volatile residue, ultraviolet absorption, and heavy metal as lead were performed as per Finemedix's design control system.

The non-clinical testing results demonstrate that the subject device is substantially equivalent to the predicate device.

Conclusion:

Clear-Jet Injection Catheter constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate device. Therefore, Clear-Jet Injection Catheter and its predicate are substantially equivalent.