October 20, 2021

Chongqing Jinshan Science & Technology Co., Ltd.
Qing Xu, RA
Yubei District No.18 Ningshang Avenue
Jinshan International Industrial City
Chongqing, Chongqing 400000
CHINA

Re: K210618
Trade/Device Name: Beamer Aveo Irrigation Pump, Endolinq Endoscopic Irrigation Pump, Endoscopic Irrigation Pump Series
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: February 26, 2021
Received: March 1, 2021

Dear Qing Xu:

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 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.

510(k) Number *(if known)*

K210618

Device Name

Endoscopic Irrigation Pump Series

Indications for Use *(Describe)*

The Endoscopic Irrigation Pump Series is indicated for endoscopic irrigation for use with washing catheters, integral endoscope water jet channels and endoscope working channels.

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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5. 510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

5.1 Submitter Information

Company:	Qing Xu RA Chongqing Jinshan Science & Technology Co., Ltd. No.18, Nishang Road, LiangLu Industrial City, 401120 Yubei District Chongqing, Chongqing China Telephone: (0086)023-86098111 Fax: (0086)023-86098777 xuq@jinshangroup.net
Contact:	Qing Xu RA Chongqing Jinshan Science & Technology Co., Ltd. No.18, Nishang Road, LiangLu Industrial City, 401120 Yubei District Chongqing, Chongqing China Telephone: (0086)023-86098111 Fax: (0086)023-86098777 xuq@jinshangroup.net
Date Summary Prepared:	February 26, 2021

5.2 Name of the Device

Trade Name:	Endoscopic Irrigation Pump Series
Common Name:	Endoscopic Irrigation/Suction System
Classification Name:	Gastroenterology/Urology
Review Panel:	Gastroenterology & Urology (GU)
Regulation:	876.1500
Class:	Class II
Product Code:	OCX

5.3 Equivalence Claimed to Predicate Device

The Endoscopic Irrigation Pump Series is equivalent to the Endogator Advantage Irrigation Pump, Model EPA-500 (K113119), manufactured by BYRNE MEDICAL, INC.. Endogator Endoscopy Irrigation Pump, Model

EGP-100 (K060962) is provided as a secondary predicate device.

5.4 Indication for Use Statement

The Endoscopic Irrigation Pump Series is indicated for endoscopic irrigation for use with washing catheters, integral endoscope water jet channels and endoscope working channels.

5.5 Device Description

The Endoscope Irrigation Pump Series (Beamer AVEOTM Irrigation Pump "AVEOPUMP" and ENDOLINQ Endoscopic Irrigation Pump "JSFP-2") is the second-generation irrigation pump developed by Chongqing Jinshan. Both models can provide an adjustable flow-rate from 0-1000 mL/min, and the pump flow can be adjusted in 100 mL/min increments, total 10 configurations available. The series works by turning a peristaltic roller pump head to move liquid through a tube set and into an endoscopic system. The pump head will not operate if the pump head is open, and will cease to operate if the pump head is opened while the motor is activated.

5.6 Substantial Equivalence Discussion

The following table compares the Endoscopic Irrigation Pump Series to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

5.7 Non-Clinical Performance Data

To demonstrate safety and effectiveness of Endoscopic Irrigation Pump Series and to show substantial equivalence to the predicate device, Jinshan completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The Endoscopic Irrigation Pump Series passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

5.8 Clinical Performance Data

N/A

5.9 Statement of Substantial Equivalence

The Endoscopic Irrigation Pump Series has the same intended use as the predicate devices, and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the Endoscopic Irrigation Pump Series is as safe and effective as the predicate device. Therefore, the Endoscopic Irrigation Pump Series is substantially equivalent to the predicate device.