February 23, 2024

Shanghai Kindly Medical Instruments Co., Ltd
Xu Jianhai, RA Manager
No.925, Jinyuan yi Road
Shanghai, 201803, China

Re: K230999
Trade/Device Name: INT Vacuum Locking Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: PUR
Dated: January 19, 2024
Received: January 23, 2024

Dear Jianhai 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 (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,

Shruti N. Mistry -S

Shruti Mistry, MS
Assistant Director
Division of Drug Delivery and General
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230999

Device Name
INT Vacuum Locking Syringe

Indications for Use *(Describe)*
INT Vacuum Locking Syringe is intended for use only by physicians for adult patients to inject fluids into, or withdraw fluids from the body. It can also be used in cases where a Vacuum Syringe is preferred (e.g., thrombus, abscess fluid, bile, urine, etc.)

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.

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K230999- 510(k) summary

I. Submitter

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Date of Preparation: February 23, 2024

II. Proposed Device

Device Trade Name:	INT Vacuum Locking Syringe
Common name:	Vacuum Locking Syringe
Regulation Number:	21 CFR 880.5860
Regulatory Class:	Class II
Product code:	PUR
Review Panel:	General Hospital

III. Predicate Devices

Primary predicate device

510(k) Number:	K163597
Trade name:	VacLok™ AT Vacuum Syringe

IV. Device description

The INT Vacuum Locking Syringe is used to inject or withdraw fluids from the body. It can also be used in cases where a vacuum syringe is preferred (e.g., thrombus, abscess fluid, bile, urine etc.). The Syringe consists of graduation lines, zero line, luer connector, nozzle lumen, seals, barrel, plunger, push-button, barrel flanges, locking column, locking piece and fiducial line. When the Syringe is used, it can be divided into two situations: normal suction in normal state and vacuum suction in locked state. Vacuum Locking Syringe is placed in a soft blister box which is composed of Tyvek 2FS and PE. The proposed device is sterilized by EO and intended for single use. The packaging form is sealed packaging and guarantees that the product is sterile until opening. The packaging can ensure the sterility of the sterilized finished

device during its shelf life of 3 years.

V. Indication for use

INT Vacuum Locking Syringe is intended for use only by physicians for adult patients to inject fluids into or withdraw fluids from the body. It can also be used in cases where a Vacuum Syringe is preferred (e.g., thrombus, abscess fluid, bile, urine, etc.)

VI. Comparison of technological characteristics with the predicate devices

Comparisons of subject device and the predicate devices shows that technological characteristics of the subject device such as components, design, sterilization, shelf life and operating principle are substantially equivalent to the currently marketed predicate device.

Table 1 summarizes the proposed device technological characteristics with compared to the predicate device under K163597.

Table 1 Technological Characteristics Comparison

Item	Proposed device	Primary predicate device (K163597)	Discussion
Product name	INT Vacuum Locking Syringe	VacLok™ AT Vacuum Syringe	-
Product Code	PUR	PUR	Same
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	Same
Class	Class II	Class II	Same
Indications for Use	INT Vacuum Locking Syringe is intended for only use by physician for adult patient to inject fluids into or withdraw fluids from the body. It can also be used in cases where a Vacuum Syringe is preferred (e.g., thrombus, abscess fluid, bile, urine, etc.)	VacLok™ AT Vacuum Syringe is used to inject fluids into or withdraw fluids from the body. It can also be used in cases where a vacuum syringe is preferred (e.g., thrombus, abscess fluid, bile, urine, etc.).	Similar
Intended user	The device is intended to be used only by physicians who has	Unknown	The different intended user populations do not alter the intended use of the device, nor do

	been trained in this device and/or has the clinical use experiences.		they affect the performance of the device.
Intended Patient Population	Adult patient	Unknow	This difference does not alter suitability of the proposed device for its intended use.
Contraindications	There are no contraindications.	There are no contraindications or warnings for this product	The proposed device contains warnings, which are to remind users to use the product safely, so this difference does not raise new or different questions of safety and effectiveness of the subject device when compared to the predicate device.
Design	The proposed INT Vacuum Locking Syringe consists of plunger, barrel, seals and locking column. Fitting offered with male luer lock connector.	Standard piston syringe constructed with a clear hollow barrel into which is inserted aclosely fitting movable plunger and tip/seal. Fitting offered with male luer lock connector.	The subtle differences in design does not affect the function of the product and the design principles are consistent. Differences in design between the predicate device and subject device were addressed through performance testing accordingly.
Material	The barrel is constructed from PC. The plunger and locking column from ABS material; Seals are made of silicone material.	The barrel is constructed from clear polycarbonate; the plunger from ABS material; the seal is made of silicone material.	The materials of the proposed device is similar to the predicate device and the biocompatibility test results show that the proposed device does not raise new biological issues regarding safety when compared to the predicate device.

Principle of Operation	Manually operated by advancing and withdrawing the plunger within the barrel.	Manually operated by advancing and withdrawing the plunger within the barrel.	Same
Vacuum Technology	Fixed stop position technology	Variable camlock technology	The difference in the Vacuum Technology does not raise new or additional questions of safety and effectiveness of the subject device when compared to the predicate device. Differences in Vacuum Technology between the predicate device and subject device were addressed through performance testing accordingly.
Operational Volume	1mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL and 60mL	20 and 30 mL	The difference in the Operational Volume does not raise new or different questions of safety and effectiveness of the subject device when compared to the predicate device. Differences in Operational Volume between the predicate device and subject device were addressed through performance testing accordingly.
Tip (nozzle) type	Fixed male luer lock connector	Fixed male luer lock connector	Same
Graduation	Printed with accurate graduation lines that are compliant with ISO 7886-1.	Printed with accurate graduation lines that are compliant with ISO 7886-1.	Same

Environment of use	Professional medical conditions	Professional medical conditions	Same
Accessories	No	No	Same
Performance Standards Used	ISO 7886-1:2017 ISO 80369-7:2021	ISO 7886-1 ISO 594-2	Same
Sterile	Yes	Yes	Same
Single for Use	Yes	Yes	Same
Prescription (Rx Only)	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Shelf life	3 years	3 years	Same

VII. Non-Clinical Testing

The non-clinical tests were conducted to verify that the proposed device met all design specifications and is substantially equivalent to the predicate device.

- **Biocompatibility testing**

The biocompatibility evaluation for proposed device was conducted in accordance with FDA's biocompatibility guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"." All tests prescribed in guidance for an external communicating device with limited exposure (≤ 24hrs) to blood path, indirect were done. The following tests were performed and passed:

- In Vitro Cytotoxicity
- Skin Sensitization
- Intracutaneous Toxicity
- Acute Systemic Toxicity
- Pyrogen
- In Vitro Hemolytic Properties

- **Performance testing**

The non-clinical bench performance testing was conducted on the subject device. Results of the testing demonstrate that the subject device met the acceptance criteria sufficient for its intended use. Testing included the following from these standards:

Items	**Methodology/Standards**
Appearance	ISO 7886-1:2017, ISO 80369-7:2021
Graduated scale	
Barrel	
Luer connector	
Nozzle lumen	
Force to operate the piston	
Freedom from air and liquid leakage past plunger stopper	
Tolerance on graduated capacity	
Dead space	
Push-button distance	
Matching of seals and plunger	
Matching of barrel and Piston	
Tensile strength	
Particulate Matter	USP<788> Particulate Matter in Injections
Titration acidity or alkalinity Limits for extractable metals Reducing (oxidizable) matter	In-house standards

- **Sterile Barrier Packaging Test**

Sterile barrier packaging testing were performed on the proposed device, which included visual inspection (ASTM F1886/F1886M-16), seal strength (ASTM F88/F88-15), dye penetration test (ASTM F1929-15) and Durability of markings test (ISO 20417:2021). The test result showed that the device package can maintain its integrity.

- **Sterilization and Shelf Life**

The sterilization method has been validated per ISO 11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Vacuum Locking Syringe is three (3) years, determined based on stability studies which includes accelerated aging.

Sterilization and shelf-life testing listed were performed on the proposed device.

Item	Standard
EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>
Shelf-Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The proposed device has the same indications and has similar design features and technological characteristics as the predicate device. Performance testing data demonstrates that the proposed device is as safe and effective as the predicate device. Accordingly, the proposed device is substantially equivalent to the predicate device.