WARNING LETTER

Jiangsu Shenli Medical Production Co., Ltd.

MARCS-CMS 677753 — MARCH 18, 2024

Product:

Medical Devices

Recipient:

Liqun Yang

General Manager

Jiangsu Shenli Medical Production Co., Ltd.

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Issuing Office:

Center for Devices and Radiological Health

United States

United States

WARNING LETTER

CMS # 677753

March 11, 2024

Dear Mr. Yang,

The United States Food and Drug Administration (FDA) has learned that your firm is marketing Jiangsu Shenli Medical Production Co. Ltd. piston syringes of the sizes and configurations listed in Table 1 below in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Model #	Item Description	Model #	Item Description
83077	SYR 30ML L/S	91839	SYR 20ML L/L YELLOW
83078	SYR 30ML L/L	91840	SYR 3ML L/L PURPLE
83079	SYR 60ML L/S	91841	SYR 5ML L/L PURPLE
83080	SYR 60ML L/L	91842	SYR 10ML L/L PURPLE
83081	SYR 10ML L/S	91845	SYR 20ML L/L BLUE SALINE

83082	SYR 10ML L/L	91846	SYR 10ML L/L YELLOW CONT
83083	SYR 3ML L/S	91847	SYR 10ML L/L BLUE LIDO
83084	SYR 3ML L/L	91849	SYR 10ML L/L BLUE SALINE
83085	SYR 5ML L/S	91850	SYR 10ML L/L RED LIDO
83087	SYR 20ML L/S	91851	SYR 10ML L/L RED HEPARIN
83088	SYR 20ML L/L	91852	SYR 5ML L/L YELLOW NITRO
83089	SYR 1ML TB	91854	SYR 10ML L/L YELLOW LIDO
91820	SYR 3ML L/L RED	91855	SYR 10ML L/L YELLOW HEP/SALINE
91821	SYR 3ML L/L GREEN	91856	SYR 10ML L/L RED CONT
91822	SYR 3ML L/L BLUE	91857	SYR 10ML L/L GREEN CONT
91825	SYR 5ML L/L RED	91858	SYR 20ML L/L WHITE SALINE
91826	SYR 5ML L/L GREEN	91859	SYR 5ML L/L PURPLE NITRO
91827	SYR 5ML L/L BLUE	91863	SYR 20ML L/L YELLOW LIDO
91828	SYR 5ML L/L WHITE	91866	SYR 5ML L/L RED NITRO
91829	SYR 5ML L/L YELLOW	91867	SYR 5ML L/L BLUE HEPARIN
91830	SYR 10ML L/L RED	91872	SYR 10ML L/S BLUE
91831	SYR 10ML L/L GREEN	91873	SYR 10ML L/L WHITE LIDO
91832	SYR 10ML L/L BLUE	91874	SYR 10ML L/S RED
91833	SYR 10ML L/L WHITE	91876	SYR CNTRL 10ML L/L YEL 1
91834	SYR 10ML L/L YELLOW	91877	SYR CNTRL 10ML L/IL YELLOW LIDO
91835	SYR 20ML L/L RED	91878	SYR CNTRL 10 ML L/L RED
91836	SYR 20ML L/L GREEN	91879	SYR CNTRL 10ML L/L GRN
91837	SYR 20ML L/L BLUE	91880	SYR CNTRL 10ML L/L BLUE
91838	SYR 20ML L/L WHITE	91881	SYR 10ML L/L CONTROL

Table 1. List of Jiangsu Shenli Medical Production Co. Ltd. piston syringe configurations implicated in this Warning Letter.

Under section 201(h) of the Act, 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

FDA has determined, based on information provided by your firm and information available on the Agency's public databases, that the Jiangsu Shenli Medical Production Co. Ltd. piston syringes configurations listed in **Table 1** are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(0(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The devices are also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm introduced or delivered for introduction into interstate commerce for commercial distribution these devices with (1) major changes or modifications to the intended use, and/or (2) a change or modification in the device that could significantly affect the safety or effectiveness of the device without submitting a premarket notification to FDA as required by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR 807.81(a)(3)(i)-(ii).

Specifically, the Jiangsu Shenli Medical Production Co. Ltd. Piston Syringe (5cc Luer Lock) was cleared under K103830 with the following indications for use: The intended use of the Jiangsu Shenli Medical Production Co., Ltd. 5cc luer lock piston syringe is to inject fluids into or withdraw fluids from the body. Based on FDA's

evaluation of your firm's activities, there is evidence that your firm is engaged in the distribution of syringes for use within the United States with substantially different technological characteristics, namely sizes other than 5 mL, luer slip instead of luer lock tips, syringes intended for specific drugs, different colors (i.e., colorants), and control syringes, each of which constitute a significant change or modification in design that could significantly alter the safety or effectiveness of the device. For further explanation on the need for a new premarket notification, or "510(k)," for changes to the intended use or design affecting safety and effectiveness, it is recommended you consult the guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device — Guidance for Industry and Food and Drug Administration Staff (fda.gov)." In the guidance at Figure 3 — Flowchart B: Technology, Engineering, and Performance Changes, FDA explains why changes in size, color, specific drug indications and connector type all constitute a major change or modification to the device's intended use, for which your firm lacks clearance or approval.

As discussed above the products listed in **Table 1** are misbranded because you made one or more change(s) or modification(s) to each device that could significantly affect the safety or effectiveness of the device without submitting a 510(k) to FDA. Specifically, changing the volume of the syringe, switching from a luer lock to a luer slip syringe tip, and changing from a traditional syringe to a control syringe could result in the risk of patient harm such as inaccurate dosing, a leaking device, a higher risk of inappropriate needle detachment, and incorrect device handling. Furthermore, the addition of color additives to your syringe could result in adverse health effects such as allergic reactions, skin irritation or inflammation, pain, fever, red blood cell damage that induces organ stress, and toxicity that leads to loss of organ function or failure. Labeling the syringe for a specific drug can also cause harm because differences in drug viscosities impact the function of the syringe and can result in patient harm such as inaccurate dosing or incorrect drug usage.

Your firm's failure to submit 510(k)s for these devices has prevented FDA from evaluating the risks posed by these substantially different technological characteristics or from determining that there is reasonable assurance of the safety and effectiveness of these modified devices such that they may be legally marketed syringes. Further, FDA has observed evidence of postmarket safety signals indicating product quality issues that have the potential to cause serious patient harm. Specifically, FDA is aware of multiple customer complaints regarding quality issues (e.g. cracks, breakage during use) for syringes in surgical kits supplied by Jiangsu Shenli Medical Production Co. Ltd.

For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

FDA requests that Jiangsu Shenli Medical Production Factory cease any activities that result in the misbranding or adulteration of all the Jiangsu Shenli Medical Production Co. Ltd. piston syringe configurations listed in **Table 1**, such as the commercial distribution of the device sizes, configurations, and uses discussed above, including selling to initial importers, distributors, or other third parties for distribution and use within the United States or otherwise representing these devices to have the requisite clearance or authorization for marketing in the United States.

Given the serious nature of the violations of the Act and growing evidence of potential harm, all the Jiangsu Shenli Medical Production Co. Ltd. piston syringes configurations listed in **Table 1** are subject to refusal of admission under section 801(a) of the Act, 21 U.S.C. § 381(a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these devices into the United States, until these violations are addressed.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to address the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address any violations included in this Warning Letter. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration as part of your response.

Your firm's response should be sent by email to CDRHWamingLetterResponses@fda.hhs.gov or by mail to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Regulatory Programs
Division of Regulatory Programs 2: Establishment Support
Regulatory Inspections and Audits Team
White Oak Building 66
10903 New Hampshire Ave.
Silver Spring, MD 20993

Refer to the identification number **CMS # 677753** when replying. We remind you that only written communication is considered as official. If you have any questions about the contents of this letter, please contact: Shruti Misty at Shruti.Mistry@fda.hhs.gov.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm. It is your firm's responsibility to ensure compliance with the applicable laws and regulations administered by FDA.

Sincerely yours,
/S/

Kellie B. Kelm, Ph.D.
Acting Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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