November 21, 2023

Suzhou Savicred Biotechnology Co., Ltd.
℅ Ryan Li
Consultant
ICAS Group
155 Pingbei Rd, Minghang
Shanghai, 201100
China

Re: K230287
Trade/Device Name: SaviSafe Safety Device
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG
Dated: October 12, 2023
Received: October 16, 2023

Dear Ryan Li:

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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230287

Device Name
Savisafe Safety Device

Indications for Use *(Describe)*
The Savisafe Safety Device is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients, from accidental needlesticks. The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.

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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510(K) Summary
K230287

I. Date Prepared [21 CFR 807.92(a)(1)]

13th October, 2023

II. Submitter Information [21 CFR 807.92(a)(1)]

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III. Device Information [807.92(a)(2)]

Name of Device: Savisafe Safety Device
Regulation Number: 21 CFR PART 880.5860
Common Name: Syringe, Antistick
Classification Name: Piston syringe
Regulatory Class: II
Product Code: MEG

IV. Identification of Predicate Device [807.92(a)(3)]

Name of Device: UltraSafe Passive PLUS Needle Guard (K123743)
Regulation Number: 21 CFR 880.5860
Common Name: Syringe, Antistick
Classification Name: Piston syringe
Regulatory Class: II
Product Code: MEG

V. Device Description [807.92(a)(4)]

The proposed device, Savisafe Safety Device is a non-sterile, single use anti-needlestick accessory for pre-filled ISO standard glass syringe that are 1ml with a needle length of 1/2".

The proposed device consists of four components:(1) Syringe sleeve, (2) Syringe holder, (3) Plunger rod, (4) Spring. The proposed device has a five-year shelf life.

VI. Intended Use

The Savisafe Safety Device is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients, from accidental needlesticks. The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.

VII. Indications for Use [21 CFR 807.92(a)(5)]

The Savisafe Safety Device is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients, from accidental needlesticks. The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.

VIII. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

The Savisafe Safety Device is compared with the predicate device, UltraSafe Passive PLUS Needle Guard (K123743). The results are shown below in the Technological Characteristics Comparison Table:

DEVICE	Savisafe Safety Device	UltraSafe Passive PLUS Needle Guard (K123743)	Remark
Indication for Use	The Savisafe Safety Device is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients, from accidental needlesticks. The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.	Single use devices that are indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients, from accidental needlesticks. The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration. Additionally, the PLUS device is designed with a larger viewing window indicated where phanna company offering is a low fill volume and instructions request visualization. The PLUS device is designed with a robust plunger and built in extended finger flanges indicated where pharma customer offering is viscous.	Similar **Note 1**
Classification Product Code	MEG	MEG	Same
Prescription Only or Over the Counter	Prescription	Prescription	Same
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same
Use	Single Use	Single Use	Same
Contraindication	None	None	Same
Configuration	Syringe sleeve Syringe holder Plunger rod Spring	Guard body Plunger Spring	Similar **Note 2**

Compatible Syringes	Pre-filled ISO Standard glass syringes	Pre-filled ISO Standard glass syringes	Same
Syringe Size	1ml	1ml	Same
Needle Length	1/2" length	1/2" length	Same
Safety Feature Mechanism	Passive Safety Feature	Passive Safety Feature	Same
Biocompatibility	**Cytotoxicity**:Under the conditions of the study, the subject device extract was determined to be non-cytotoxic. **Irritation**:Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating. **Sensitization**:Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non- sensitizing.	Unknown	N/A
Sterilization	Non-sterile	Non-sterile	Same

Discussion in details:

Note 1: Both the proposed device and the predicate device are safety feature device used with pre-filled glass syringe to prevent sharps injury. The extra description of the predicate device's indications for use would not affect the substantial equivalence between the proposed device and the predicate device.

Note 2: Although the configuration of the proposed device is not the same as the predicate device, corresponding comparison performance tests are conducted on both the proposed device and the predicate device. The test result is shown the substantial equivalence. Therefore, the substantial equivalence between the proposed device and the predicate device is not affected by the configuration difference.

IX. Performance Data

Non-Clinical Performance Test Conclusion

Biocompatibility

The proposed device, Savisafe Safety Device is categorized as skin contact with a duration of category A-limited(≤24hrs) according to FDA guidance ***Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part1: Evaluation and testing within a risk management process"***. The Biocompatibility tests were conducted to verify that the proposed devices are not adverse to human tissue based on the following standards:

- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:20101Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity

Safety Feature Performance

Performance tests regarding the safety feature are conducted both on the proposed device and the predicate device according to ISO 23908:2011 including:

- Safety Feature Activation Force Test
- Safety Feature Override Force Test

The test results shown that the proposed device is substantial equivalence with the predicate device.

Other performance tests are conducted to meet the design specification of the proposed device including:

- Free-fall Test
- Activation Reaction
- Access to the sharp in safe mode

Compatibility Performance

Tests regarding proposed device with compatible pre-filled syringe are conducted to demonstrate the compatibility between the proposed device and the pre-filled syringe.

Simulated Transportation

A test is conducted according to ASTM D4169:2022 to demonstrate the proposed device could function as intended after transportation.

Simulated Clinical Study

In addition, a simulated clinical use study is conducted on the subject device, Savisafe Safety Device to evaluate the effect of safety feature per FDA Guidance "Medical Devices with Sharps Injury Prevention Features" issued on August 9, 2005. The test results demonstrated that the subject device complies with the requirements.

Clinical Test Conclusion

No clinical study is included in this submission.

X. CONCLUSION

The conclusion drawn from the non-clinical tests demonstrates that the proposed device, Savisafe Safety Device is as safe, as effective, and performs as well as or better than the legally marketed predicate device UltraSafe Passive PLUS Needle Guard(K123743).