December 29, 2022

Roncadelle Operations srl
Massimo Rossi
Quality & Regulatory Manager
Via Renolda 10
Castel Mella (Brescia), Lombardia 25030
Italy

Re: K221981
Trade/Device Name: SafeR Syringe and SafeR Sting
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMI, FMF
Dated: November 16, 2022
Received: December 1, 2022

Dear Massimo Rossi:

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,

Courtney Evans -S
Digitally signed by Courtney Evans -S
Date: 2022.12.29 10:45:46 -05'00'

For Alan Stevens
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221981

Device Name
SafeR Syringe and SafeR Sting

Indications for Use *(Describe)*
SafeR® is an automatically Retractable Safety Syringe, it is intended to provide a safe, accurate and reliable method for the aspiration of fluids and for the injection of fluids immediately after filling. It is intended to be used for the administration of medications (intramuscular (IM), intradermal (ID) and subcutaneous (SC)). SafeR® system is provided in 2 separate parts: SafeR Syringe and the needle group SafeR Sting. Before use, the end user needs to assemble syringe and needle group. The syringe, once assembled with his needle, incorporates a passive safety mechanism which retracts and contains the contaminated needle after use, aiding in prevention of possible infection due to needlestick injuries and syringe re-use. Needle retraction is activated by the syringe user with one hand. SafeR Sting blunt fill needle is designed only for drug preparation and it is not intended to come in contact with human body. SafeR Syringe with SafeR Sting maintain standard injection techniques.

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.

510(k) Summary K221981

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

1. Submitter Information

Company:	Roncadelle Operations srl Via Renolda 10 Castel Mella (Brescia), Lombardia 25030 Italy Telephone: + 39 030 672 4322
Contact:	Massimo Rossi Quality & Regulatory Manager Roncadelle Operations srl Via Renolda 10 Castel Mella (Brescia), Lombardia 25030 Italy Telephone: + 39 030 672 4322 massimo.rossi@roncadelle-operations.com
Date Summary Prepared:	December 27, 2022

2. Device Name and Classification

Trade Name:	SafeR Syringe and SafeR Sting
Common Name:	Safety syringe and retractable needle
Classification Name:	Syringe, Antistick
Review Panel:	General Hospital
Regulation:	880.5860
Class:	Class II
Product Code:	MEG, FMI, FMF

3. Predicate Device

The SafeR Syringe and SafeR Sting is equivalent to the WTF SECURA SYRINGE AND NEEDLE (K132120), manufactured by BEIJING WANTEFU MEDICAL APPARATUS Co., Ldt..

4. Indication for use

SafeR® is an automatically Retractable Safety Syringe, it is intended to provide a safe, accurate and reliable method for the aspiration of fluids and for the injection of fluids immediately after filling. It is intended to be used for the administration of medications (intramuscular (IM), intradermal (ID) and subcutaneous (SC)).
SafeR® system is provided in 2 separate parts: SafeR Syringe and the needle group SafeR Sting. Before use, the end user needs to assemble syringe and needle group. The syringe, once assembled with his needle, incorporates a passive safety mechanism which retracts and contains the contaminated needle after use, aiding in prevention of possible infection due to needlestick injuries and syringe re-use. Needle retraction is activated by the syringe user with one hand. SafeR Sting blunt fill needle is designed only for drug preparation, and it is not intended to come in contact with human body. SafeR Syringe with SafeR Sting maintain standard injection techniques.

5. Device Description

SafeR® (SafeR Syringe and SafeR Sting) is an automatically retractable safety syringe, it is intended to provide a safe, accurate and reliable method for the aspiration of fluids or for the injection of fluids immediately after filling.

SafeR® system is composed by a body syringe (SafeR Syringe) and a needle group (SafeR Sting). SafeR Syringe and SafeR Sting are 2 (two) products, packaged and sold separately, but designed to be coupled for use. Before use, the end user needs to assemble the body syringe and needle group through a clockwise rotation. Body syringe and needle group are connected by means of a threaded connection and conical mating surfaces between Screw Connector and Barrel. Geometry of the threaded connection was designed to ensure appropriate coupling only between SafeR Sting screw connector and SafeR Syringe barrel. Once assembled with its needle (SafeR Sting), incorporates a passive safety mechanism which retracts and contains the contaminated needle into a hollow stem of the plunger after use, aiding in the prevention of possible infections due to needle stick injuries and syringe reuse. Needle retraction is activated by the syringe user with one hand.

Its intended condition is sterile, single use, for hospital or home use.

6. Substantial Equivalence Comparison

Substantial Equivalence Table			
Characteristic	**Proposed Device: SafeR Syringe and SafeR Sting**	**Primary Predicate Device: WTF SECURA SYRINGE AND NEEDLE (K132120)**	**Same /Similar /Different**
Intended Use	SafeR® (SafeR Syringe and SafeR Sting) is an automatically Retractable Safety Syringe, it is intended to provide a safe, accurate and reliable method for the aspiration of fluids and for the injection of fluids immediately after filling. It is intended to be used for the administration of medications (intramuscular (IM), intradermal (ID) and subcutaneous (SC)). The syringe, once assembled with its needle, incorporates a passive safety mechanism which retracts and contains the contaminated needle after use, aiding in the prevention of possible infections due to needle stick injuries and syringe re-use. Needle retraction is activated by the syringe user with one hand.	The WTF Secura Syringe (with needle) is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin. The WTF Secura Syringe (with needle) has a manually attached WTF Secura Retracting Needle. The WTF Secura Syringe (with needle) contains an inner passive safety mechanism used to allow the WTF Secura Retracting Needle to be retracted inside the plunger rod of the syringe when operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needlesticks during normal handling and disposal of the used needle/ syringe combination.	Similar (Intended use of subject device falls within the intended use of predicate device)

Indication for Use	SafeR® is an automatically Retractable Safety Syringe, it is intended to provide a safe, accurate and reliable method for the aspiration of fluids and for the injection of fluids immediately after filling. It is intended to be used for the administration of medications (intramuscular (IM), intradermal (ID) and subcutaneous (SC)). SafeR® system is provided in 2 separate parts: SafeR Syringe and the needle group SafeR Sting. Before use, the end user needs to assemble syringe and needle group. The syringe, once assembled with his needle, incorporates a passive safety mechanism which retracts and contains the contaminated needle after use, aiding in prevention of possible infection due to needlestick injuries and syringe re-use. Needle retraction is activated by the syringe user with one hand. SafeR Sting blunt fill needle is designed only for drug preparation and it is not intended to come in contact with human body. SafeR Syringe with SafeR Sting maintain standard injection techniques.	The WTF Secura Syringe (with needle) is used for aspiration of fluids from vials and ampoules anda variety of fluid injections below the surface of the skin. The WTF Secura Syringe (with needle) has a manually attached WTF Secura Retracting Needle. The WTF Secura Syringe (with needle) contains an inner passive safety mechanism used to allow the WTF Secura Retracting Needle tobe retracted inside the plunger rod of the syringe when operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needlesticks during normal handling and disposal of the used needle/ syringe combination.	Similar (Indication for use of subject device falls within the indication for use of predicate device)
Device Configuration and Materials	Barrel: Polypropylene Plunger: Polypropylene Plunger stopper: Lubricated Isoprene rubber Safety mechanism spring: Stainless Steel Needle hub and screw connector: Polypropylene Needle: stainless steel Syringe and Needle Lubricant: Silicone Medical	Barrel: Polypropylene Plunger: Polypropylene Plunger seal: Lubricated Isoprene rubber Safety mechanism spring: Stainless Steel Needle hub: Polypropylene Needle: stainless steel Syringe and Needle Lubricant: Silicone Medical	Same

Syringe Volume	SafeR Syringe and SafeR Sting 1/2/2.25/3/5 ml	Syringe volume: 1/2.5/3/5/10 ml	Similar (the proposed device has syringe volumes 1/2/2.25/3/5 ml that fall within the volume range of the predicate device (1/2.5/3/5/10 ml)
Syringe Design	Piston Syringe (Syringe Antistick) with hypodermic single lumen needle	Syringe Design: Piston Syringe (Syringe Antistick) with hypodermic single lumen needle	Same
Needle Design	Tip Type: Tri-Beveled Tip Needle tip configuration: Regular point	Needle Design: Tri-Beveled Tip	Same
Connection	Needle hub luer lock connector. Needle & syringe separable	Needle hub luer lock connector. Needle & syringe separable	Same
Safety features	Passive safety feature, manually activated by user	Passive safety feature, manually activated by user	Same
Needle length tolerances	Conform to ISO 7864	Conform to ISO 7864	Same
Needle system colour coding	Conform to ISO 6009	Conform to ISO 6009	Same
Syringe Dimension characteristics	Barrel flanges sizes are adequate to enable the syringe to be held securely according to ISO 7886-1	Conform to ISO 7886-1	Same
Barrel Transparency	Clear as required by ISO 7886-1	Clear as required by ISO 7886-1	Same
Gradation legibility	Legible as per ISO 7886-1 requirements	Conform to ISO 7886-1	Same
Tolerance on graduated capacity	Conform to ISO 7886-1	Conform to ISO 7886-1	Same
Graduated scale characteristics	Conform to ISO 7886-1 requirements	Conform to ISO 7886-1	Same
Deliver accuracy/ capacity	Conform to ISO 7886-1	Conform to ISO 7886-1	Same

Barrel performances	Dead space lower than upper specification given in ISO 7886-1; Safer Syringes are free from air and liquid leakage and there is no plunger stopper detachment as per ISO 7886-1 requirements	Conformity to ISO 7886-1 claimed	Same
Syringe limits for acidity or alkalinity and for extractables metals	When tested according to the method described in ISO 7886-1 The pH value of distilled water exposed to the finish syringe product does not change more than 1 unit and the overall content of metals (lead, tin, zinc and iron) does not exceed 5mg/kg	Conformity to ISO 7886-1 is claimed	Same
Syringe lubricant amount	< 0.25mg/cm2 as per ISO 7886-1 requirements	Conformity to ISO 7886-1 is claimed	Same
Retractable Needles gauge and length	20 G – 1" 1 ¼" and 1 ½" 21 G - 1" 1 ¼" and 1 ½" 22 G - 1" 1 ¼" and 1 ½" 23 G - 1" 1 ¼" and 1 ½" 25 G – 5/8" and 1" 26 G – 5/8" and 1" 27 G - ½"	21 G - 1 1/8" and 1 ¼" 22 G – 1 ¼ and 1" 23 G – 1" 25 G – 1" 30 G 1"	Similar (The proposed device has a higher choice of needle lengths and gauges respect to the predicate device.)
Dosing needle gauge and length	18G - 1 ¼"	18G – 1"	Similar
Needle performances	In accordance with ISO 7864 requirements, needle point is sharp and free from defects, needle surface is smooth and free from defects and needle-hub bonding strengths are higher than the specification given in the standard	Conformity to ISO 7864 is claimed	Same
Sharp Injury protection feature and reuse prevention feature performances	Conform to ISO 7886-4 and ISO 23908	Conform to ISO 7886-4 (alleged compliance to ISO 23908 given the claimed compliance to 7886-1 in which it is stated "Syringes with integrated or add-on sharps protection shall comply with ISO 23908")	Same

Primary Packaging barrier	Sterile barrier of primary packaging according to ISO 11607 1/2	Sterile barrier of primary packaging according to ISO 11607 1/2	Same
Biocompatibility	Conform to ISO 10993	Conform to ISO 10993	Same
Sterilization	SAL 10-6 EO sterilization according to ISO 11135	SAL 10-6 EO sterilization according to ISO 11135	Same
Ethylene Oxide residuals	Conform to ISO 10993-7	Conform to ISO 10993-7	Same

7. Non-Clinical Performance Testing

Table below summarizes the purpose of each test performed and the reference standard requirements.

Test	Ref. Standard requirements
Syringe Visual Inspection	ISO 7886-1:2017 ISO 7864:2016 ISO 9626:2016
Dimensional Verification	ISO 7886-1:2017 ISO 7864:2016
Syringe pH verification	ISO 7886-1:2017
Needle pH verification	ISO 7864:2016
Corrosion resistance	ISO 9626:2016
Extractables Metals	ISO 7886-1:2017
Lubricant amount	ISO 7886-1:2017 ISO 7864:2016
Needle point	ISO 9626:2016 ISO 7864:2016
Needle outer surface	ISO 7864:2016
Needle bonding strength	
Needle Penetration and Drag Force	
Volume Verification and Dead Space	ISO 7886-1:2017
Air Leakage	
Piston operating force	
Liquid Leakage	
Sharp Injury protection feature activation	ISO 23908:2011 ISO 7886-4:2018
Access the device in the safe mode	ISO 23908:2011
Positive pressure Liquid leakage	ISO 80369-7:2021 ISO 80369-20:2015
Sub-atmospheric pressure air leakage	
Resistance to separation from axial load	
Resistance to separation from unscrewing	
Usability Test	EN 62366-1:2020

Health Care Workers SafeR Usability Evaluation	
Visual Inspection for Packaging	ASTM F1886/F1886M- 16
Bubble leak test	UNI EN ISO 11607-1:2021, ASTM F2096-11 (2019)
Peeling strength seal bond	ASTM F88-F88M -15
Biological evaluation	ISO10993-1, ISO10993-5, ISO10993-10, ISO10993-11

Performance tests (bench) were conducted to verify that SafeR Syringe and SafeR Sting meet all design specifications as is substantially equivalent (SE) to the predicate device. The test results and the comparison with predicate performances show that the subject product is substantially equivalent to the predicate device in performance.

Sterile barrier packaging testing were performed on the proposed device. The test results showed that the device package can maintain its integrity.

Sterilization testing per ISO 11135 and shelf-life testing were performed on the proposed device. EO residue and Endotoxin did not exceed the limits of relevant Standards. Shelf-life test results showed that the device can maintain its performance during the claimed shelf life.

Biological evaluation for SafeR Syringe and SafeR Sting has been performed per ISO 10993-1 and all biological endpoints relevant for the biological safety assessment have been evaluated. The results of the biocompatibility testing confirm that SafeR Syringe and SafeR Sting are biocompatible in compliance for indirect blood path with limited contact duration <24hrs. Cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, and particulate testing per USP <788> were provided for both components.

8. Substantial Equivalence Conclusion

SafeR Syringe and SafeR Sting were compared to the predicate device WTF SECURA SYRINGE AND NEEDLE. Based on the evidence collected, the substantial equivalence between SafeR Syringe and SafeR Sting and predicate device has been verified. Through functional performance testing the subject device has demonstrated substantial equivalence to the predicate device.