February 21, 2023

Ranfac Corporation
Eric Kreuz
Vice President/Quality & Regulatory Affairs
30 Doherty Avenue
Avon, Massachusetts 02322

Re: K223612
Trade/Device Name: Ranfac Lateral Access Bone Marrow Aspiration Needle (CRVS-BMA-LA)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: January 25, 2023
Received: January 25, 2023

Dear Eric Kreuz:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.02.21 13:54:09 -05'00'

On behalf of
Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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.

Submission Number *(if known)*

K223612

Device Name

Ranfac Lateral Access Bone Marrow Aspiration Needle (CRVS-BMA-LA)

Indications for Use *(Describe)*

The Lateral Access Bone Marrow Aspiration Needle is intended for use for aspiration of bone marrow or autologous blood using a standard piston syringe.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Ranfac Lateral Access Bone Marrow Aspiration Needle 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

1. SUBMITTER

Sponsor: Ranfac Corp.
30 Doherty Ave
Avon, MA

Contact Person: Eric Kreuz
Vice President/Regulatory & Quality
Ph: 1-508-584-4400, Ext. 137
Fax: 1-508-584-8588
Email: ekreuz@ranfac.com

Date: December 3, 2022

2. DEVICE

Device Proprietary Name:	Ranfac Lateral Access (LA) Bone Marrow Aspiration Needle
Common or Usual Name:	Biopsy Needle
Regulatory Classification:	Class II
Classification Name:	Instrument, biopsy
Regulation:	21 CFR 876.1075
Device Regulation Panel:	Gastroenterology/Urology
Device Product Code:	KNW

3. PREDICATE DEVICE

Proprietary Name:	Ranfac Marrow Cellution Needle (K150563)
Common Name:	Biopsy Needle
Classification Name:	Instrument, Biopsy
Regulation:	21 CFR 876.1075
Product Code:	KNW
Regulatory Classification:	Class II
Classification Panel:	Gastroenterology/Urology

4. DEVICE DESCRIPTION

The Ranfac Lateral Access BMA Needle subject of this premarket notification is a manual, sterile disposable needle intended for the purpose of aspirating bone marrow or autologous blood. The device consists of an Access Needle for bone/bone marrow penetration and an Aspirator Cannula through which the aspirate is obtained. The Access Needle is comprised of a 7-gauge outer cannula and an 11-gauge inner cannula with an overall length of 6.5 inches when the inner cannula is fully extended. The outer cannula has an adjustable grip, and a blunt tip that rests on the surface of the bone. The inner cannula has a ground point for bone/bone marrow penetration and side ports for marrow aspiration. When the molded grip of the Access Needle is turned clockwise the inner cannula is withdrawn into the outer cannula exposing the tip to a different location within the needle tract allowing for additional bone marrow aspiration acquisition without having to reposition the needle.

During use, the Access Needle is inserted into bone with the aid of a sharp or drillable stylet. Once the needle is properly positioned and the stylet removed, a 14-gauge Aspiration Cannula is inserted into the Access Needle. The distal tip of the Aspiration Cannula is closed and provided with side holes to allow the physician to aspirate from the sides of the needle (to minimize blood within the aspirate). A white indicator on both the Access Needle and the Aspiration Cannula is provided in order to allow for alignment of the two components' side ports (for aspiration of bone marrow).

An exchangeable Drillable Stylet is provided for use with the device which can mate to a standard surgical drill to aid bone penetration if needed. The device is also packaged with a commercially available, 510k cleared standard 10mL luer lock hypodermic syringe for collection of bone marrow aspirate.

5. INDICATIONS FOR USE

The Ranfac Lateral Access BMA Needle is for use for aspiration of bone marrow or autologous blood using a standard piston syringe.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Ranfac FLEX BMA Needle is substantially equivalent in intended use, principles of operation and fundamental technological characteristics to the legally marketed predicate Marrow Cellution device (K150563). The table below summarizes the similarities and differences in design, materials and dimensions between the subject and predicate device.

Table 1. Comparison of the Ranfac LA BMA Needle Technological Characteristics with Predicate Ranfac Marrow Cellution Needle

	Ranfac LA BMA Needle (This Submission)	**Marrow Cellution (K150563)**
Regulation Number	21 CFR §876.1075	21 CFR §876.1075
Intended Use	For harvest of bone marrow tissue	For harvest of bone marrow tissue
Indication for Use	For use for aspiration of bone marrow or autologous blood using a standard piston syringe.	For use for aspiration of bone marrow or autologous blood using a standard piston syringe.
Performance Characteristics	Needle bores into bone to access marrow cavity	Needle bores into bone to access marrow cavity
Overall Product Design	Single-use, sterile disposable needle to acquire tissue specimen.	Single-use, sterile disposable needle to acquire tissue specimen.
Mechanics of Operation	Manual instrument	Manual instrument
Patient/Tissue Contact Materials	Stainless steel and plastic	Stainless steel and plastic
Access Needle Gauge and Length	Adjustable length between 4.8 and 6.5 inches.	Needle provided in lengths of 4 and 6 inches.
Needle Cutting Tip Configuration	Stylet has beveled 3-sided trocar tip and needle cannula has 5-sided grind tip for penetration	Stylet has beveled 3-sided trocar tip and needle cannula has 5-sided grind tip for penetration.
Aspiration Cannula Configuration	14-gauge 304 stainless steel hollow cannula with one set of side ports and ABS luer.	14-gauge 304 stainless steel hollow cannula with one set of side ports and ABS luer.
Aspiration Cannula Length	11.5 inches nominal	9.2 inches nominal
Handle Configuration	T-Shaped Handle Configuration	T-Shaped Handle Configuration
Adjustable Depth Guide	Yes	Yes
Drillable Stylet	Yes	No
10mL Hypodermic Syringe Provided	Yes	Yes
Packaging	Tyvek/Mylar Pouch	Tyvek/Mylar Pouch

Table 1. Comparison of the Ranfac LA BMA Needle Technological Characteristics with Predicate Ranfac Marrow Cellution Needle

	Ranfac LA BMA Needle (This Submission)	**Marrow Cellution (K150563)**
Sterilization	Supplied Sterile via Ethylene Oxide validated to 10^{-6} Sterility Assurance Level	Supplied Sterile via Ethylene Oxide validated to 10^{-6} Sterility Assurance Level
Shelf-Life	6 months	5 years

7. PERFORMANCE TESTING

Structural integrity testing was conducted on the Ranfac LA BMA Needle demonstrating robustness and appropriateness of the design. All samples met or exceeded acceptance criteria. Strength specifications (resistance to breakage and torque) are similar to those of the predicate Ranfac Marrow Cellution Bone Marrow Aspiration Needle. Additionally, simulated use testing was performed to validate that the design output of the Ranfac LA BMA Needle met design input requirements.

The Ranfac LA BMA Needle is provided sterile, sterilized with ethylene oxide to an assurance level of 10^{-6} in a validated cycle. Distribution simulation and shelf-life studies have been conducted to demonstrate that the device maintains its performance and the packaging will maintain its sterile barrier over the entirety of the intended shelf life.

Conclusion

Ranfac has demonstrated that the Ranfac LA BMA Needle is substantially equivalent in fundamental design, function, device materials, packaging, sterilization, operating principle, intended use/ indication for use and fundamental technology as the legally marketed predicate device Ranfac Marrow Cellution Needle, which was cleared under Premarket Notification K150563 on May 22, 2015.