September 18, 2020

Ranfac Corporation
Eric Kreuz
Vice President of Quality Assurance/Regulatory Affairs
30 Doherty Street
Avon, Massachusetts 02322

Re: K202287
Trade/Device Name: Ran-Flex-B Bone Marrow Aspiration Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: August 10, 2020
Received: August 12, 2020

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202287

Device Name
Ranfac FLEX Bone Marrow Aspiration (BMA) Needle (RAN-FLEX-B)

Indications for Use *(Describe)*
The Ranfac FLEX Bone Marrow Aspiration (BMA) Needle is intended 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.

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510(k) Summary

Submission Type: Traditional 510(k)

Submitter Information:

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Date Prepared:

August 10, 2020

Subject Device Information:

Proprietary Name:	Ranfac FLEX BMA Needle
Common Name:	Biopsy Needle
Classification Name:	Instrument, Biopsy
Regulation:	21 CFR 876.1075
Product Code:	KNW
Device Classification:	Class II
Classification Panel:	Gastroenterology/Urology

Predicate Devices:

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

The Ranfac FLEX BMA Needle is considered substantially equivalent to the Ranfac Marrow Cellution Needle cleared under 510(k) Premarket Notification K150563 on May 22, 2015 (primary predicate). The selected primary predicate is appropriate based on similarity in intended use, principle of operation as well as materials and other technological characteristics between it and the Ranfac FLEX BMA Needle. Further, the same manufacturing and sterilization processes are used by Ranfac for the subject and predicate devices.

Where differences exist between the subject and predicate device, the following devices are used to bridge these differences and therefore serves as reference predicates.

Reference Predicate Devices			
Device Trade Name:	Ranfac Bone Marrow Biopsy Needle	MarrowMiner	OnControl Bone Marrow Aspiration System
Manufacturer:	Ranfac	StemCor Systems, Inc.	VidaCare Corp. (now Teleflex)
510(k) Number:	K190177	K071732	K072045
Device Common Name:	Biopsy Needle	Biopsy Instrument	Biopsy Needle
Classification:	Biopsy Instrument / Class II per §876.1075 / Procode KNW/FCG	Biopsy Instrument / Class II per §878.4820 / Procode GDM/GAA	Biopsy Instrument / Class II per §876.1075 / Procode KNW/FCG
Classification Panel:	Gastroenterology / Urology	General & Plastic Surgery	Gastroenterology / Urology
Reason for Reference Predicate	To cover the characteristic for an 8 gauge needle	To cover the flexible shaft	To cover attribute for an exchangeable drill insert

Device Description:

The Ranfac FLEX 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 provided with an integral threaded Adjustable Guide which acts as a depth stop for control of needle penetration depth and when turned counterclockwise allows for the Aspiration Cannula to be withdrawn backwards through the bone marrow needle tract in a controlled manner (as opposed to manually pulling back the needle or Aspiration

Cannula). 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). The Aspiration Cannula has a flexed tip which will redirect if the tip encounters the wall of the marrow cavity. The Access Needle is 8 gauge with an effective length of 3 inches. 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 packaged with the following commercially available, 510k cleared accessory devices:

- Standard 10mL luer lock hypodermic syringe (Becton Dickinson K980580, cleared June 25, 1998 or equivalent 510(k) cleared hypodermic syringe)
- J-Type Bone Marrow Biopsy Needle (RJN Needle manufactured by Ranfac Corp. – reference K190177, cleared June 12, 2019 – the RJN Needle assembly includes a needle with stylet, probe tip, probe cannula and trap cannula).

Indications for Use:
The Ranfac FLEX Bone Marrow Aspiration Needle is intended for aspiration of bone marrow or autologous blood using a standard piston syringe.

Comparison of Technological Characteristics to 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. The table below summarizes the similarities and differences in design, materials and dimensions between the subject and predicate device.

Table 5-1. Comparison of the Ranfac FLEX BMA Needle with the Predicate Ranfac Marrow Cellution Needle

	FLEX 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.

Table 5-1. Comparison of the Ranfac FLEX BMA Needle with the Predicate Ranfac Marrow Cellution Needle

	FLEX BMA Needle (This Submission)	Marrow Cellution (K150563)
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. The device is comprised of an outer cannula with handle and an inner stylet and Aspiration Cannula with flexible stainless steel coil tubing tip. Includes an integral threaded Adjustable Guide that when turned counter-clockwise allows for the aspiration cannula to be withdrawn backwards through the marrow (rather than manually pulling back on the aspiration cannula). Needle has depth markings every centimeter.	Single-use, sterile disposable needle to acquire tissue specimen. The device is comprised of an outer cannula with handle and an inner stylet and an Aspiration Cannula with rigid stainless steel tip. Includes an integral threaded Adjustable Guide that when turned counter-clockwise allows for the needle to be withdrawn backwards through the marrow (rather than manually pulling back on the needle). Needle has depth markings every centimeter.
Mechanics of Operation	Manual instrument	Manual instrument
Patient/Tissue Contact Materials	Stainless steel and plastic	Stainless steel and plastic
Access Needle Gauge x Length	8 gauge by 3 inch 304 stainless steel needle with cm etched depth markings and ABS T-Handle	11 Gauge by 4 or 6 inch 304 stainless steel needle with cm etched depth markings and ABS T-Handle
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 – also provided with blunt tip stylet.

Table 5-1. Comparison of the Ranfac FLEX BMA Needle with the Predicate Ranfac Marrow Cellution Needle

	FLEX BMA Needle (This Submission)	Marrow Cellution (K150563)
Aspiration Cannula Configuration	11 gauge 316L stainless steel hollow cannula with welded flexible 316L stainless steel distal end. The very distal end of the cannula is closed with side ports for aspiration. Provided with ABS luer and snap fit T-handle. Provided with Stylet.	14 gauge x 304 stainless steel hollow cannula with one set of side ports and ABS luer.
Aspiration Cannula Working Length	9.8 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
Packaging	Components in PETG tray placed in Tyvek/Mylar Pouch	Tyvek/Mylar Pouch
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

The subject and primary predicate device differ from one another primarily with respect to gauge size (increase diameter to 8 gauge), aspiration cannula configuration (flexible vs. rigid Aspirator Cannula tip) and inclusion of an exchangeable drill insert. To bridge these differences in product characteristics between the subject FLEX Needle and primary predicate, the following reference predicates have been cited:

- For 8 gauge needle: Ranfac Bone Marrow Biopsy Needle K190177, cleared June 12, 2019
- For flexible shaft: MarrowMiner: K071732, cleared September 24, 2007
- Exchangeable drill insert: Oncontrol Bone Marrow Biopsy System K072045, cleared October 22, 2007

Performance Data

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

Biocompatibility Testing

A biocompatibility evaluation was conducted in accordance with the FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process,"* consistent with the requirements for an externally communicating device (with tissue) for a limited duration (≤24 hours). The following biocompatibility tests were successfully completed on the final, sterilized Ranfac FLEX BMA Needle:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous toxicity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

Sterility

The Ranfac FLEX BMA Needle is sterilized via a validated ethylene oxide (EO) process to a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization process was validated per ISO 11135 *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.*

Shelf Life

The Ranfac FLEX BMA Needle has a shelf life of 6-months. 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.

Clinical Performance Data

No clinical studies were deemed necessary to demonstrate the safety and effectiveness of the subject device.

Conclusion

Ranfac has demonstrated that the Ranfac FLEX 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.