June 12, 2019

Ranfac Corporation
Eric Kreuz
Director of Quality Assurance/Regulatory Affairs
30 Doherty Ave
Avon, Massachusetts 02322

Re: K190177
Trade/Device Name: Ranfac Bone Marrow Biopsy Needles (J-Type Marrow Biopsy Needle,T-Type Marrow Biopsy Needle, and Tweezer Bone Marrow Biopsy Needle)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: May 9, 2019
Received: May 13, 2019

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,

for

Jennifer R. Stevenson
Acting Division 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)*
K190177

Device Name
Ranfac Bone Marrow Biopsy Needle

Indications for Use *(Describe)*
The Ranfac Bone Marrow Biopsy Needles are indicated for use in aspirating bone marrow and for use in obtaining core biopsy samples of bone marrow.

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

I. SUBMITTER

Sponsor: Ranfac Corp.
30 Doherty Ave.
Avon, MA

Contact Person: Eric Kreuz
Date: May 9, 2017
Ph: 1-508-584-4400, Ext. 137
Fax: 1-508-584-8588

II. DEVICE

Device Trade Name: **Ranfac Bone Marrow Biopsy Needles**
Common or Usual Name: Biopsy Needle
Device Classification: Class II
Classification Name: Instrument, Biopsy
Regulation: 876.1075
Device Regulation Panel: Gastroenterology/Urology
Device Product Code: KNW & FCG

III. PREDICATE DEVICES

Ranfac Bone Marrow Aspiration Needle (K131157 – primary predicate), Ranfac Goldenberg Bone Marrow Biopsy Needle (K983187) and the CareFusion Jamshidi Bone Marrow Biopsy/Aspiration Needle (K171531).

IV. DEVICE DESCRIPTION

The Ranfac Bone Marrow Biopsy Needles subject of this premarket notification (RTN-114, RTN-116, RTN-84, RTN-86, RTN-114-T, RTN 116-T, RTN-84-T, RTN-86-T, RJN -114, RJN -116, RJN-84, RJN-86) are manual, sterile disposable needles intended for the purpose of harvesting bone marrow specimens. The device is comprised of an outer cannula with handle and an inner stylet. The cannula has graduated etched markings spaced in 1 cm intervals. The product is provided with a probe guide and marked probe to assist with the extraction of the bone marrow specimen from the needle. The probe guide facilitates the insertion of the marked probe through the distal end of the needle. The marked probe is introduced into the probe guide at the distal tip of the needle and advanced forward to move and expel the specimen out through the needle handle. Specific models of the Ranfac Bone Marrow Biopsy Needles are also provided with a stainless steel marrow extraction cannula (either Canoe or Tweezer design) which fit inside the needle to facilitate capture and retrieval of bone marrow samples. The specimen is contained within the extraction cannula during withdrawal from the needle. The Ranfac Bone Marrow Biopsy Needles are provided with a luer cap to prevent back flow of blood during needle insertion and product with the optional extraction cannula are provided with two needle vices to cap the needle and stylet tip prior to disposal.

V. INDICATIONS FOR USE

The Ranfac Bone Marrow Biopsy Needles are intended for use in aspirating bone marrow and for use in obtaining core biopsy samples of bone marrow.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Ranfac Bone Marrow Biopsy Needles are similar to the predicate Ranfac Needles in intended use (i.e., acquisition of bone marrow), fundamental scientific technology, operating principles, fundamental mechanical design, performance characteristics, packaging, sterility, shelf-life and biocompatibility. The Ranfac Bone Marrow Biopsy Needles and predicate devices share a similar basic design (needle cannula and stylet) and are provided sterile for single use, have the same materials, and operation. A comparison of the Ranfac Bone Marrow Biopsy Needles with the predicate devices is provided in **Table 5-1**. This table details the closely shared indications for use, materials and design and principle of operation between the devices, therefore establishing substantial equivalence of the devices subject of this current submission with the predicate products.

Table 5-1. Comparison of the Ranfac Bone Marrow Biopsy Needle to the Primary and Secondary Predicate Bone Marrow Biopsy Needles

	Ranfac Bone Marrow Biopsy Needle (This Submission)	**Ranfac Bone Marrow Aspiration Needle (K131157)**	**Goldenberg Bone Marrow Biopsy Needle (K983187)**	**Jamshidi Bone Marrow Biopsy/Aspiration Needle (K171531)**
Regulation Number	21 CFR §876.1075	Same	Same	Same
Intended Use	Intended for use in aspirating bone marrow and for use in obtaining cylindrical core biopsy samples of bone marrow	Intended for use in aspirating bone marrow	Intended for use in obtaining cylindrical core biopsy samples of bone marrow	Intended for use in aspirating bone marrow and for use in obtaining cylindrical core biopsy samples of bone marrow
Indication for Use	The Ranfac Bone Marrow Biopsy Needles are indicated for use in aspirating bone marrow and for use in obtaining core biopsy samples of bone marrow.	The Ranfac Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow	For procuring bone marrow core biopsies from patients with hematologic abnormalities.	Intended for the posterior iliac crest biopsy technique.

Table 5-1. Comparison of the Ranfac Bone Marrow Biopsy Needle to the Primary and Secondary Predicate Bone Marrow Biopsy Needles

	Ranfac Bone Marrow Biopsy Needle (This Submission)	**Ranfac Bone Marrow Aspiration Needle (K131157)**	**Goldenberg Bone Marrow Biopsy Needle (K983187)**	**Jamshidi Bone Marrow Biopsy/Aspiration Needle (K171531)**
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.	Same	Same	Same
Mechanics of Operation	Manual instrument	Manual Instrument	Manual Instrument	Manual Instrument
Patient/Tissue Contact Materials	Stainless steel and plastic	Stainless steel and plastic	Stainless steel and plastic	Stainless steel and plastic
Gauge x Length	8 and 11 Gauge in lengths of 4 and 6 inches	11 Gauge x 4 inches	11 Gauge	8 and 11 Gauge x 4 and 6 inches
Cannula Configuration	304 stainless steel hollow cannula with no side ports	304 stainless steel hollow cannula with side ports	316L stainless steel with internal polyurethane molded spiral snare	Stainless steel hollow cannula with multiple cutting edges and no side ports
Stylet Configuration	Solid stainless-steel wire	Same	Same	Same
Handle Configuration	"T-Style" mating plastic handle on cannula and stylet	"T-Style" mating plastic handle on cannula and stylet	"T-style" mating aluminum handle on cannula and threaded retainer knob on stylet	Mating plastic handle on cannula
Needle Cutting Tip Configuration	Beveled Swaged Needle Tip	5-point Needle Tip	5-point Needle Tip	Beveled Swaged Needle Tip

Table 5-1. Comparison of the Ranfac Bone Marrow Biopsy Needle to the Primary and Secondary Predicate Bone Marrow Biopsy Needles

	Ranfac Bone Marrow Biopsy Needle (This Submission)	**Ranfac Bone Marrow Aspiration Needle (K131157)**	**Goldenberg Bone Marrow Biopsy Needle (K983187)**	**Jamshidi Bone Marrow Biopsy/Aspiration Needle (K171531)**
Bone Marrow Extraction Accessories	Probe guide and probe provided to expel tissue specimen from needle cannula – Tweezer and Canoe Extraction Cannula optionally provided	None: tissue is aspirated through needle using standard hypodermic syringe.	Spiral snare internal to needle is used to capture and retain tissue	Probe guide and probe provided to expel tissue specimen from needle cannula – some versions of the Jamshidi needle are provided with a specimen cradle which is a component similar to the extraction cannulas provided with the Ranfac needle.
Packaging	Tyvek/Mylar Pouch	Tyvek/Mylar Pouch	Tyvek/Mylar Pouch	Tyvek/Mylar Pouch
Sterilization	Supplied sterile via Ethylene Oxide validated to 10^{-6} Sterility Assurance Level	Same	Same	Supplied sterile via Gamma irradiation
Shelf-Life	5 years	5 years	Not stated in K983187	5 years

The differences between the Ranfac Bone Marrow Biopsy Needles and predicate Ranfac Bone Marrow Aspiration Needle include the addition of the 8 gauge and 6 inch length needles, as well as the addition of the bone marrow extraction accessories; i.e., probe guide, marked probes and extraction cannula used to facilitate retrieval of a trephine biopsy. These changes have been incorporated to adapt for user preferences. Additionally, the Ranfac Bone Marrow Biopsy Needle has a swaged needle tip vs. a 5-point tip configuration to facilitate coring of bone. The predicate Jamshidi Bone Marrow Biopsy/Aspiration Needles (reference K171531) classified under 21 CFR §876.1075 (procode KNW) is provided in sizes of 8 and 11 gauge, lengths of 4 and 6 inch, with swaged needle tip and with an extraction cannula (referred to as a marrow acquisition or "specimen" cradle) and probe for retrieving and expelling the tissue sample.

Similar to the Ranfac Goldenberg Bone Marrow Biopsy and Jamshidi Bone Marrow Biopsy/Aspiration Needles, the needles subject of this 510k are used to obtain a trephine biopsy (i.e., "core-type" biopsy"); whereas, the predicate Ranfac Bone Marrow Aspiration Needle has side holes on the needle cannula to allow for bone marrow acquisition via aspiration. Both types of tissue samples (trephine core biopsy and aspirate) are important to the diagnosis of hematological disorders. The general procedures and guidelines in the Ranfac Bone Marrow Biopsy Needle labeling provide instructions for biopsy sample collection.

In summary, the changes were appropriately assessed through risk analysis activities and do not raise any new or significant questions of safety or effectiveness. The Ranfac Bone Marrow Biopsy Needles are substantially equivalent to the predicate devices presented.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing:

The Ranfac Bone Marrow Biopsy Needle has been demonstrated to be biocompatible with passing results for the following testing:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic toxicity
- Material-Mediated Pyrogenicity

The Ranfac Bone Marrow Biopsy Needles are considered tissue contacting for a duration of less than 24 hours.

Bench Testing:
Structural integrity testing (tensile/torque) was conducted on the Ranfac Bone Marrow Biopsy Needles demonstrating robustness and appropriateness of the design. All samples met or exceeded acceptance criteria. Testing was consistent with methods used for the predicate Ranfac Bone Marrow Aspiration Needle. Comparative performance testing using the Jamshidi Bone Marrow Biopsy/Aspiration Needle for reference demonstrates that the Ranfac Bone Marrow Biopsy Needle are suitably designed for bone marrow sampling. Additionally, simulated use testing was performed to validate that the design output of the Ranfac Bone Marrow Biopsy Needles met design input requirements.

Clinical Studies:
No clinical studies were conducted for this submission.

VIII. CONCLUSION

Performance testing and comparison of characteristics between the subject and predicate devices have demonstrated that the Ranfac Bone Marrow Biopsy Needles are substantially equivalent to the predicate devices with regard to intended use (harvest of a bone marrow specimen), operation, function, and technological characteristics, all devices being manually operated to obtain a bone marrow specimen.