April 25, 2019

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

Re: K183146
Trade/Device Name: Ranfac Cartilage Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: November 8, 2018
Received: November 13, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.04.25 06:21:18 -04'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K183146

Device Name
Ranfac Cartilage Biopsy Needle

Indications for Use *(Describe)*
The Cartilage Biopsy Needle is intended to obtain a sample of articular cartilage tissue during arthroscopy.

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: March 23, 2019
Ph: 1-508-588-4400, Ext. 137
Fax: 1-508-584-8588

II. DEVICE

Device Trade Name: Ranfac Cartilage Biopsy Needle
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). This device has not been subject to a design-related recall.

A reference predicate for this device is the CareFusion Jamshidi-Type Bone Marrow Biopsy/Aspiration Needle (K171531).

IV. DEVICE DESCRIPTION

The Ranfac Cartilage Biopsy Needle is a manual, sterile disposable needle intended to obtain a sample of cartilage during arthroscopy. The device is comprised of an outer cannula with handle and an inner stylet. The product is provided with probe guide and probe to assist with the extraction of the cartilage from the needle. The probe guide facilitates the insertion of the probe through the distal end of the needle. The 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. This premarket notification is for both an 8-gauge and 11-gauge needle (product catalog numbers: CBN-84 and CBN-114, respectively).

V. INDICATIONS FOR USE

The Cartilage Biopsy Needle is intended to obtain a sample of articular cartilage tissue during arthroscopy.

The Indications for Use statement for the Cartilage Biopsy Needle is not identical to the predicate device which is used for obtaining a sample of bone marrow; however, the differences do not alter the high-level intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices are used to harvest a tissue specimen near bone.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Ranfac Cartilage Biopsy Needles ("CBN)" are similar to the predicate Ranfac Bone Marrow Aspiration Needle ("BMA Needle" - K131157) in intended use (i.e., acquisition of tissue), fundamental scientific technology, operating principles, fundamental mechanical design, performance characteristics, packaging, sterility, shelf-life and biocompatibility. The proposed and predicate devices share a similar design (needle cannula and stylet) and are provided sterile for single use, have the same materials, and operate in the Ranfac CBN with the primary predicate Ranfac BMA Needle is provided in **Table 5-1**. This table details the closely shared indications for use, materials and design and principle of operation therefore establishing substantial equivalence of the proposed device with the presently commercialized predicate product.

Table 5-1. Comparison of the Proposed Ranfac Cartilage Biopsy Needle to the Primary Predicate Ranfac Bone Marrow Aspiration Needle

	Ranfac Cartilage Biopsy Needle (This Submission)	**Ranfac Bone Marrow Aspiration Needle (K131157)**
Regulation Number	21 CFR §876.1075	Same
Intended Use	For harvest of a tissue sample/tissue biopsy	Same
Indication for Use	The Ranfac Cartilage Biopsy Needle is intended to obtain a sample of articular cartilage tissue during arthroscopy.	The Ranfac Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow
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. The device is provided in two gauge sizes; i.e., 8 gauge (CBN-84) and 11 gauge (CBN-114).	Single-use, sterile disposable needle to acquire tissue specimen. The device is comprised of an outer cannula with handle and an inner stylet. The device is an 11-gauge needle.
Mechanics of Operation	Manual instrument	Manual instrument
Patient/Tissue Contact Materials	Stainless steel and plastic	Stainless steel and plastic
Gauge x Length	8 and 11-Gauge x 4 inches	11 Gauge x 4 inches

Table 5-1. Comparison of the Proposed Ranfac Cartilage Biopsy Needle to the Primary Predicate Ranfac Bone Marrow Aspiration Needle

	Ranfac Cartilage Biopsy Needle (This Submission)	**Ranfac Bone Marrow Aspiration Needle (K131157)**
Cannula Configuration	304 stainless steel hollow cannula with no side ports	304 stainless steel hollow cannula with side ports
Stylet Configuration	Solid stainless-steel wire	Same
Handle Configuration	Mating plastic handle on cannula and stylet	Same
Sample Extraction Accessories	Probe guide and probe provided to expel tissue specimen from needle cannula	None: tissue is aspirated through needle using standard hypodermic syringe.
Packaging	Tyvek/Mylar Pouch	Same
Sterilization	Supplied Sterile via Ethylene Oxide validated to 10^{-6} Sterility Assurance Level	Same
Shelf-Life	5 years	5 years

The differences between the proposed and predicate devices is that the Ranfac CBN is intended for acquisition of cartilage; whereas, the Ranfac BMA needle is used to acquire bone marrow, both bone marrow aspirate and cartilage can be characterized as soft tissues and in both cases the needles must penetrate bone for purposes of acquiring the target tissue. The Ranfac BMA Needle is an 11-gauge needle and includes side-holes for aspiration of the bone marrow; whereas, the Ranfac CBN is provided in an 8 and 11-gauge configuration and without side holes. The Ranfac CBN is provided with a probe to facilitate tissue acquisition. These differences are not unique to the Ranfac CBN. The Jamshidi-type Bone Marrow Biopsy/Aspiration Needles (reference K171531) classified under 21 CFR §876.1075 (procode KNW) is provided in both an 8 gauge and 11-gauge configuration (no side ports on needle cannula), and provided with a probe for expelling the tissue sample. Both the Ranfac CBN and the reference Jamshidi-type needle acquire a solid core of tissue (trephine biopsy) using similar methods. The general procedures and guidelines in the proposed Ranfac CBN device's labeling provide instructions for cartilage biopsy sample collection.

In summary, the proposed changes were appropriately assessed and do not raise any new or significant questions of safety or effectiveness. The proposed device is 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 biocompatibility evaluation for the Ranfac CBN was conducted in accordance with FDA's Guidance "Use of International Standard ISO-10993-1, "Biological evaluation of medical devices Part 1: Evaluation and Testing Within a Risk Management Process," as published by FDA on June 16, 2016. The battery of testing included the following tests with passing results for all:

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

The Ranfac CBN is considered tissue contacting for a duration of less than 24 hours.

Bench Testing:
Structural integrity testing (tensile/torque) was conducted on the Ranfac CBN demonstrating robustness of the design. All samples met or exceeded acceptance criteria. Additionally, testing was performed to demonstrate that the Ranfac CBN was suitably designed for its intended purpose; i.e., acquisition of a cartilage biopsy, while maintaining the integrity of the sample as evaluated via histological analysis in a model in which articular cartilage was harvested from ex vivo bovine knees.

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 CBN is substantially equivalent to the primary and reference predicate devices with regard to intended use (biopsy for harvest of a tissue specimen), operation, function, and technological characteristics.