DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2015

Ranfac Corporation
Mr. Christopher Whelan
Senior Vice President
30 Doherty Avenue, P.O. Box 635
Avon, Massachusetts 02322

Re: K150563
Trade/Device Name: Marrow Cellution Bone Marrow Aspiration Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: March 4, 2015
Received: March 6, 2015

Dear Mr. Whelan:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

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

510(k) Summary

The contents of this 510(k) summary on the following pages have been provided in conformance with 21 CFR PP 807.92 "content and format of a 510(k) summary".

1. Submitter/Sponsor

Ranfac Corp.
30 Doherty Avenue
Avon, MA 02322
FDA Registration Number 1211566
Telephone Number/Fax: 508-588-4400 ext. 106/508-584-8588
Contact Person: Christopher P. Whelan
Date Prepared: March 04, 2015

2. Device Name

Trade Name: Marrow Cellution Bone Marrow Aspiration Needle
Common or Usual Name: Aspiration Needle
Classification Name: Gastroenterology-Urology Biopsy Instrument
21 CFR §876.1075, Product Code KNW
Classification: Class II

3. Predicate Device:

Trade Name	510(k)	Company
Ranfac Aspiration Needle with Adjustable Guide	K140991	Ranfac Corp.
Ranfac Bone Marrow Aspiration Needle	K131157	Ranfac Corp.

4. Device Description

The Marrow Cellution Bone Marrow Aspiration Needle consists of a Ranfac Aspiration Needle with Adjustable Guide as well as an additional Aspirator Cannula and a 10ml Syringe.

The Marrow Cellution Bone Marrow Aspiration Needle is a single use disposable needle that allows the medical device professional the ability to aspirate from the sides of the needle without aspirating from the needle tip. This allows the needle to be retracted during aspiration ensuring aspirate will not be compromised by the end being open to an area that has already had aspirate removed.

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5. Indications For Use

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

6. Comparison of the Technological Characteristics With the Predicate Devices:

As compared with the predicate devices, and as shown below, the Marrow Cellution Bone Marrow Aspiration Needle has the same indications for use, and has similar technological and operational characteristics when compared with the predicate devices.

Table 5.1 Comparison of the Proposed Marrow Cellution Bone Marrow Aspiration Needle to the Ranfac Aspiration Needle with Adjustable Guide and Ranfac Bone Marrow Aspiration Needle

	Marrow Cellution Bone Marrow Aspiration Needle (This Submission)	Ranfac Aspiration Needle with Adjustable Guide (K140991)	Ranfac Bone Marrow Aspiration Needle (K131157)
Intended Use	The Marrow Cellution Bone Marrow Aspiration Needle is intended for use for aspiration of bone marrow or autologous blood using a standard piston syringe.	The Ranfac Aspiration Needle with Adjustable Guide is intended for use for aspiration of bone marrow or autologous blood using a standard piston syringe.	The Ranfac Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow.
Design	Sterile, Disposable	Sterile, Disposable	Sterile, Disposable
Performance Characteristics	Needle bores into bone to access marrow cavity	Needle bores into bone to access marrow cavity	Needle bores into bone to access marrow cavity
Cannula Configuration	Hollow Outer Cannula with cutting edges without side ports Hollow Inner Cannula with closed end and side ports	Hollow Cannula with cutting edges without side ports	Hollow Cannula with cutting edges with or without side ports
Stylet Configuration	Trocar Tip and Blunt Tip	Trocar Tip and Blunt Tip	Trocar Tip
Ga. Size	11Ga.	11Ga.	11Ga. & 8Ga.
Handle Configuration	Handle is Molded to Cannula Handle is Molded to Stylet	Handle is Molded to Cannula Handle is Molded to Stylet	Handle is Molded to Cannula Handle is Molded to Stylet
Materials: Handles Cannula/Stylet	ABS AISI 304 Stainless Steel (tested per ISO 9626)	ABS AISI 304 Stainless Steel (tested per ISO 9626)	ABS AISI 304 Stainless Steel (tested per ISO 9626)
Sterilization	Supplied Sterile (Ethylene Oxide)	Supplied Sterile (Ethylene Oxide)	Supplied Sterile (Ethylene Oxide)

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7. Performance Data

Design verification tests were performed based on the risk analysis and product requirements, and the results of these tests demonstrate that the Marrow Cellution Bone Marrow Aspiration Needle performed in an equivalent manner to the predicate devices and is safe and effective when used as intended. Design verification test reports are included in **Section 18.**

Biocompatibility information is consistent with the requirements of ISO 10993-1 Biological evaluation of medical devices Part 1: Evaluation and Testing, and therefore the materials used in the manufacture of the Marrow Cellution Bone Marrow Aspiration Needle are suitable for their intended use. Biocompatibility information is included in **Section 15.**

8. Clinical Data

Not applicable.

9. Conclusion

Based on the similarities in indications for use, materials, design, principles of function, biocompatibility and sterilization between the Marrow Cellution Bone Marrow Aspiration Needle, subject of this premarket notification, and the predicate devices, the proposed subject device has been shown to be substantially equivalent to the predicate devices in accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act.