Precision instruments for specialized applications

SECTION 5

510(k) Summary

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

K131157

510(k) Summary

OCT 2 2 2013

Owner's Name and Address:

Ranfac Corporation
30 Doherty Avenue
Avon, MA 02322-0635
FDA Registration Number 1211566

Official Contact Person:

Christopher P. Whelan
Senior Vice President – Quality
Telephone: 508-588-4400 extension: 106
Facsimile: 508-584-8588
e-mail: cwhelan@ranfac.com

Date Summary Prepared:

October 21, 2013

Device Trade Name:

Ranfac Bone Marrow Aspiration Needle

Common Name:

Aspiration Needle, BMA Needle

Classification Name: Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW

Precision instruments for specialized applications

510(k) Summary

Predicate Device:

510(k) Number	Predicate Description	Manufactured By
K050795	Imbibe Bone Marrow Aspiration Needle	Orthovita, Inc.
K100665	MarrowMax Bone Marrow Aspiration Needle Kit	NeedleTech
K051506	Sterylab Best Bone Harvesting System	Sterylab

Device Description:

The Ranfac Bone Marrow Aspiration Needle is a single-use aspiration needle comprised of a stainless steel cannula with a molded plastic handle, and a stainless steel stylet with a molded plastic handle which mates with the cannula handle when the stylet is inserted through the cannula. While holding the mated handles, the user rotates the needle using a clockwise-counter clockwise motion while applying pressure on the bone. The needle bores into the marrow cavity. Once there the stylet is removed and aspiration is accomplished by attaching a luer syringe (not included) to the needle and applying negative pressure.

Intended Use:

The Ranfac Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow.

Technological Characteristics:

The Ranfac Bone Marrow Aspiration Needle is similar in materials and design to the predicate device. Both devices are comprised of stainless steel tubing for the cannula and stainless steel wire for the stylet. Both devices have plastic molded handles for the cannula and stylet that mate with each other to prevent separation. Both devices have side holes or no side holes to maximize aspiration and both have luer lock connections enabling the use of standard syringes.

Precision instruments for specialized applications

510(k) Summary

Non-clinical Data: Standards

The Stainless Steel, which is the only patient contacting material, and contacts the patient in a limited use is in conformance with ISO 9626 First edition 1991-09-01, Amendment 1 2001-06-01 Stainless steel needle tubing for the manufacture of medical devices. FDA Standards Recognition Number 6-163.

The luer lock connection that is molded as part of the plastic handle is in conformance with ISO 594/1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements. FDA Standards Recognition Number 6-11.

The luer lock connection that is molded as part of the plastic handle is in conformance with ISO 594-2 Second edition 1998-09-01, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings. FDA Standards Recognition Number 6-129.

The following standards apply to the sterilization of the finished device.

ISO 11135-1, Sterilization of health care products – Ethylene Oxide – Part1: Requirements for development, validation and routine control of a sterilization process for medical devices. FDA Recognition Number 14-331.

ISO 10993-7, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals. FDA Recognition Number 14-335.

AAMI/ANSI/ISO 14161:2009,Sterilization of health care products – Biological indicators – Guidance for the selection, use and interpretation of results. FDA Recognition Number 14-285

Precision instruments for specialized applications

	ISO 11607-1:2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems. FDA Recognition Number 14-355
Clinical Data:	Not applicable
Conclusion:	Based on the similarities in materials, design, principles of function, biocompatibility and sterilization between the Ranfac Bone Marrow Aspiration Needle, subject of this premarket notification and the predicate device, the Ranfac Bone Marrow Aspiration Needle has been shown to be substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.

RANFAC CORP. | PO BOX 635 | 30 DOHERTY AVE | AVON, MA 02322 | USA
Phone: 508-588-4400 | 800-272-6322 | Fax: 508-584-8588 | Email info@ranfac.com
www.ranfac.com

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

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

October 22, 2013

Re: K131157
Trade/Device Name: Ranfac 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 23, 2013
Received: August 29, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

Indications for Use

510(k) Number (if known): K131157

Device Name: **Ranfac Bone Marrow Aspiration Needle**

Indications for Use: **The Ranfac Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow.**

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A — Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.10.22 06:51:26 -04'00'

for MXM

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K131157