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

September 11, 2017

CareFusion
Tamara Brey
Regulatory Affairs Manager
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K171531
Trade/Device Name: Jamshidi Bone Marrow Biopsy/Aspiration Needle, Jamshidi T-Handle Bone Marrow Biopsy/Aspiration Needle, Jamshidi Evolve Bone Marrow Biopsy/Aspiration Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: August 29, 2017
Received: August 31, 2017

Dear Tamara Brey:

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 (DICE) 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" (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 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 (DICE) 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,

Jennifer R. Stevenson -S3

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171531

Device Name
Jamshidi Bone Marrow Biopsy/Aspiration Needles

Indications for Use *(Describe)*

Jamshidi Bone Marrow Biopsy/Aspiration Needle – DJ: Intended use for the posterior iliac crest biopsy technique.

Jamshidi T-Handle Bone Marrow Biopsy/Aspiration Needle - TJ: Intended use for the posterior iliac crest biopsy technique.

Jamshidi Evolve Bone Marrow Biopsy/Aspiration Needle - EJ: Indicated for use in aspirating bone marrow and for use in obtaining core biopsy samples of bone and/or 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.

510(k) SUMMARY – K171531

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion
Address	75 North Fairway Drive, Vernon Hills, IL 60061 USA
Phone number	(847) 362-9285
Fax number	(312) 949-9245
Establishment Registration Number	1423507
Name of contact person	Tamara Brey
Date prepared	September 7, 2017
DESCRIPTION OF DEVICE	
Trade or proprietary name	Jamshidi® Bone Marrow Biopsy/Aspiration Needle Jamshidi® T-Handle Bone Marrow Biopsy/Aspiration Needle Jamshidi® Evolve Bone Marrow Biopsy/Aspiration Needle
Common or usual name	Bone Marrow Biopsy Needle
Classification name	Gastroenterology-urology biopsy instrument
Classification panel	Gastroenterology/Urology
Regulation	Class II per 21CFR §876.1075
Product Code	KNW
Legally marketed device(s) to which equivalence is claimed	K813338, K913306, K003370, and K070091.
Device description	The Jamshidi® devices are manual, sterile, disposable needles intended to obtain bone marrow aspirate and core biopsy samples from bone and/or bone marrow. The devices are comprised of an outer cannula with a handle and an inner stylet. Some models include a marrow acquisition cradle (MAC) or a specimen cradle. The MAC and specimen cradle fit inside the cannula to capture and retrieve samples by mechanically cutting the core sample. The specimen is contained within the cradle during withdrawal from the cannula.
Intended use of the device	Jamshidi Bone Marrow Biopsy/Aspiration Needle – DJ: Intended use for the posterior iliac crest biopsy technique. Jamshidi T-Handle Bone Marrow Biopsy/Aspiration Needle – TJ: Intended use for the posterior iliac crest biopsy technique. Jamshidi Evolve Bone Marrow Biopsy/Aspiration Needle – EJ: Indicated for use in aspirating bone marrow and for use in obtaining core biopsy samples of bone and/or bone marrow.

DEVICE COMPARISON TO PREDICATE DEVICE

The Jamshidi® Bone Marrow Biopsy/Aspiration Needles are the same to the predicate devices in the intended use, target population, fundamental scientific technology, operating principles, fundamental mechanical design, performance characteristics, packaging, sterility and biocompatibility.

The technological characteristics of the proposed Jamshidi® Bone Marrow Biopsy/Aspiration Needles utilizes the same basic components as identified in the predicate Jamshidi® devices to achieve its intended use: a cannula, handle, inner stylet and a marrow acquisition cradle (MAC) or a specimen cradle in some models. The proposed and predicate devices are for single use, have the same materials, and operate manually to access bone marrow.

The differences between the proposed and predicate devices include an expanded range of needle lengths, introduction of centimeter depth markings to facilitate placement, a new needle tip geometry, an updated specimen cradle design, and a new depth stop accessory. The general procedures and guidelines in the proposed device's labeling were updated to provide clarity and facilitate biopsy sample collection.

In summary, the proposed changes were appropriately assessed and do not raise any new or significant questions of safety and efficacy. The proposed devices are substantially equivalent to the predicate devices presented.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE - PERFORMANCE TEST SUMMARY

Bench-top testing (pull testing, torque testing, sharpness testing) was conducted on EJ devices. Simulated use testing was conducted on DJ, TJ and EJ devices. Comparative testing (sharpness testing, simulated use testing) was conducted on JBC devices. All testing was successfully completed, showing with reasonable assurance that the proposed CareFusion's Jamshidi Bone Marrow Biopsy/Aspiration Needles meet or exceed all performance requirements, and are substantially equivalent to the predicate devices.

Characteristic	Standard/Test/FDA Guidance
Risk Management	BS EN ISO 14971:2012 Medical Devices. Application of Risk Management to Medical Devices
Packaging	AAMI / ANSI / ISO 11607-1:2006/(R)2010 [Including: Amendment 1 (2014)] Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems And Packaging Systems
Packaging	AAMI / ANSI / ISO 11607-2:2006/(R)2010, [including: amendment 1 (2014)]. Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
Biocompatibility	ANSI/AAMI/ISO 10993-1:2009 (R) 2013 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process
Biocompatibility	ANSI/AAMI/ISO 10993-4:2002 Amendment 1 2006 Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood
Biocompatibility	ANSI/AAMI/ISO 10993-5:2009 (R) 2014 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
Biocompatibility	ANSI/AAMI/ISO 10993-7:2008 (R) 2012 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
Biocompatibility	ANSI/AAMI/ISO 10993-10:2010 (R) 2014 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
Biocompatibility	ANSI/AAMI/ISO 10993-11:2006 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity

Biocompatibility	ANSI/AAMI /ISO 10993-12:2012 Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials
Biocompatibility	ANSI/AAMI/ISO 10993-17:2002 (R) 2012 Biological Evaluation of Medical Devices – Part 17: Establishment of Allowable Limits for Leachable Substances
Biocompatibility	ISO 10993-18: 2005 Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials
Sterilization	ISO 11135:2014 Sterilization of Health Care Products – Ethylene Oxide Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
Sterilization	ISO 11138-1: 2006/(R) 2010 Sterilization of Health Care Products - Biological Indicators - Part 1: General Requirements
Sterilization	ISO 11737-1:Second Edition 2006-04-01 Sterilization of Medical Devices - Microbiological Methods - Part 1
Sterilization	AAMI TIR28:2009/(R)2013 Product Adoption and Process Equivalency for Ethylene Oxide Sterilization
Sterilization	AAMI/ANSI/ISO 11137-1:2006/(R) 2010 Including: Amendment 1 (2013) Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices
Stability	ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
N/A – No clinical tests were conducted for this submission	
CONCLUSION OF DEVICE COMPARISON	
The Jamshidi Bone Marrow Biopsy/Aspiration Needles are equivalent to the predicate devices in that: - The devices have the same intended use. - The devices have substantially equivalent design, function and areas of application. - The devices demonstrate substantially equivalent performance.	