DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 17, 2014

Vidacare, LLC
Ms. Diana F. Montez, BSN, RN
Research, Clinical and Regulatory Assistant
4350 Lockhill Selma Road
Shavano Park, Texas 78023

Re: K142377
Trade/Device Name: The OnControl™ Bone Marrow Biopsy System by Vidacare®
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: November 14, 2014
Received: November 17, 2014

Dear Ms. Montez:

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,

Binita S. Ashar -S

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)*
K142377

Device Name
The OnControl Bone Marrow Biopsy System by Vidacare

Indications for Use *(Describe)*
The OnControl Bone Marrow Biopsy System is intended for bone marrow aspiration and biopsy in adult and pediatric patients age 2 and older.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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008_ 510(k) Summary [807.92(c)]

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K142377

SUMMARY

Submitter's name [807.92(a)(1)]: Vidacare LLC

Address: 4350 Lockhill Selma Road
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Phone: 210-375-8500

Fax number: 210-375-8537

Name of contact person: Diana Montez, BSN, RN
diana.montez@teleflex.com

Date Summary was prepared: July 10, 2014

[807.92(a)(2)]:
Trade Name of the device: The OnControl™ Bone Marrow Biopsy System by Vidacare®
Common or usual name: Bone Marrow Biopsy Needle (21 CFR 876.1075, KNW, FCG)
Classification name: Gastroenterology-Urology Biopsy Instrument

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

510(k) number	***Trade or Proprietary or Model Name***	***Manufacturer***
K072045	The OnControl™ Bone Marrow System by Vidacare®	Vidacare Corporation
K070759	Powered EZ-IO® Pediatric Bone Marrow Aspiration System (new trade name, OnControl Bone Marrow Aspiration System).	Vidacare Corporation

Device Description [807.92(a)(4)]:

The OnControl Bone Marrow Biopsy System by Vidacare® consists of a reusable Power Driver and a disposable sterile needle set in a sealed procedure tray. The procedure tray contains 1 driver connector with sterile sleeve, 1 biopsy needle set with depth guide, an ejector rod and alignment guide. The OnControl Bone Marrow Biopsy System Needle Set consists of a cannula made of 304 stainless steel, with a beveled cutting tip and stylet. The needle sets are 11 gauge, 102 mm and 152 mm with an internal core capturing thread at the distal tip of the cannula. The proposed device will utilize identical needle sets (gauge, length and materials) as currently utilized in the predicate device K072045 The OnControl Bone Marrow Biopsy System by Vidacare®. The proposed device will also utilize the power rotary driver technology as used for the predicates K072045, The OnControl Bone Marrow Biopsy System by Vidacare® and K070759 Powered EZ-IO® Pediatric Bone Marrow Aspiration System (new trade name, OnControl Bone Marrow Aspiration System).

Upon activation, the power rotary driver assists the clinician in inserting the needle set through the cortex of the bone. The driver is then separated from the hub of the needle set by retracting the OnControl Connector release mechanism. The inner stylet is used only to penetrate the cortex and is then removed. The standard Luer lock hub on the cannula permits attachment of a syringe for aspiration. The depth guide which slides up and down the cannula is moved to the desired depth marking. The power rotary driver is then reattached to the biopsy cannula and the driver is activated and advanced the desired depth to obtain the biopsy specimen and then withdrawn. The driver is then separated from the needle assembly for specimen removal.

This submission requests the addition of the pediatric population, age 2 and older, as an expanded indication to previously cleared K072045, The OnControl Bone Marrow Biopsy System with the same Indication For Use, for bone marrow aspiration and biopsy utilizing the same insertion technique and devices as the predicate.

(Proposed) Indications for Use:
The OnControl™ Bone Marrow Biopsy System is intended for bone marrow aspiration and biopsy in adult and pediatric patients age 2 and older.

Proposed Expanded Indication Discussion:

Reason for requested expanded indication: This device expanded indication will enhance the diagnostic abilities of physicians trained in the retrieval of bone/bone marrow biopsy samples from pediatric patients with addition of an option to traditional manual devices (with their associated poor rates of adequate specimen retrieval).[1,2] This could possibly improve patient outcomes by offering an option when clinicians believe the control and rotary driver will obtain better bone marrow biopsy samples with fewer attempts (allowing for less time under anesthesia with associated potential risks) for diagnostic accuracy, and faster access to treatment when necessary.

Overview: Bone marrow evaluation is essential for the diagnosis of hematological malignancies and non-malignant disease in children; and is also useful for staging certain diseases and response to therapy.[3] Core biopsy length has been found to be critical in diagnoses, relapse prediction or identifying residual disease post-chemotherapy. The larger the amount of marrow obtained the greater chance of finding a focal lesion.[4]

The current practice of obtaining trephine biopsies and bone marrow aspirates in children via the manual method has a poor success rate for obtaining adequate specimens. In a study by the European Neuroblastoma Study Group, 139 of 822 (17%) biopsy specimens were inadequate; containing less than 0.5 cm of well-preserved bone marrow as assessed by two central reviewers. In 13 institutions submitting at least 20 cores, failure rates ranged from 2.6 to 50%.[1] Reid, et al. reported 25% of 605 pediatric trephine biopsies were inadequate.[2]

Safety and Efficacy Considerations (includes non-clinical test summary): The results of a recent randomized controlled trial with pediatric patients (ranging from 2-18 years old) requiring a bone marrow biopsy demonstrate that the OnControl™ Bone Marrow Biopsy System by Vidacare® product is safe and effective for bone marrow biopsy in pediatric patients. Researchers concluded that the OnControl™ Bone Marrow Biopsy System obtained biopsies safely, in less time and of good quality when compared with traditional manual biopsy retrieval methods.[5]

The powered rotary technology for obtaining aspirations in pediatric patients previously cleared with predicate K070759, Powered EZ-IO® Pediatric Bone Marrow Aspiration System (new trade name, OnControl Bone Marrow Aspiration System) has been used safely without any reported complications since clearance in 2007. The powered technology and rotary driver design of Vidacare's vascular access devices have proven

safe for the indication of vascular access in pediatric bones, including the FDA cleared sites of proximal humerus, and the proximal and distal tibia and distal femur.

The OnControl Bone Marrow Biopsy System, K072045, is currently cleared for use in adults only. Multiple studies have evaluated the use of the OnControl system in adults and found decreased time of procedure, decreased pain, and improved core biopsy specimens when compared with traditional manual biopsy methods.[6,7,8,9,10] Swords et al demonstrated the OnControl system yielded core specimens that were of superior size and quality when compared to the manual technique in a randomized controlled trial in adults.[7] There have been no reported serious complications for either of the Vidacare predicates reported from the literature or the FDA MDR system since clearance in 2007 for K070759 in pediatric patients or K072045 in adults.

A tactile feedback study was designed to address concerns that the power rotary driver design, a component of the OnControl Bone Marrow and Biopsy System, might limit procedural control and the ability of clinicians to discern catheter tip location when accessing bone. This study compared the ability of clinicians to attain precision of needle tip placement by tactile feedback only when using three devices (two manual devices and the power rotary device) in simulated bone. The Vidacare power rotary driver had an insertion success rate of 97% compared with 48.5% for the traditional manual biopsy needle.[11]

[807.92(b)(3)]:

Conclusion:

In consideration of published studies, the cited clinical study, the safety record of both the predicate devices, and also the experience with the rotary powered technique of the EZ-IO vascular access devices we conclude that adding the pediatric population to expand the indications for use of K072045 is safe and effective, using the same technique and equipment. The only change to the proposed Directions for Use labeling would be the addition of the pediatric population age 2 and older to the indications.

[807.92(a)(5)]:

(Proposed) Indications for Use:

The OnControl™ Bone Marrow Biopsy System is intended for bone marrow aspiration and biopsy in adult and pediatric patients age 2 and older.

[807.92(a)(6)]:

Summary of the technological characteristics of this device compared to the predicate devices:

The expanded indication requires no new technology to facilitate the safe application of the product. There have been no changes to the design or components of the devices cleared under K072045 and therefore, the comparison of technological characteristics listed below are identical:

- Driver Design Features
- Firmware
- Needle Design
- Technique
- Anatomical sites
- Sterility
- Where Device is Used
- Biocompatibility
- Ergonomics of the patient-user interface

References (available upon request):

1. Reid MM, Roald B. Adequacy of bone marrow trephine biopsy specimens in children. *J. Clin. Pathol*. 1996;49:226-229
2. Reid MM, Roald B. Deterioration in performance in obtaining bone marrow trephine biopsy cores from children. *J. Clin. Pathol*. 1999;52:851-852.
3. Abla O, Friedman J, and Doyle J. Performing bone marrow aspiration and biopsy in children: Recommended guidelines. *Paediatr Child Health* 2008; 13:499-501.
4. Islam A and Henderson ES. Value of long-core biopsy in the detection of discrete bone marrow lesions. *Histopathology* 1988;12:641-648.
5. Falcon-Cantrill M, Thomas P, Saldivar V, Assanasen C. Comparison of a rotary powered bone marrow aspiration and biopsy device to the traditional manual device in children. *Pediatr Blood Cancer* 2013;60(S2);S8. Doi:10.1002/pbc.24509 (Full manuscript pending publication)
6. Cohen SC, Gore JM. Evaluation of a powered intraosseous device for bone marrow sampling. *Anticancer Research* 2008;28:3843-3846
7. Swords RT, Anguita J, Higgins RA, et al. A prospective randomised study of a rotary powered device (OnControl) for bone marrow aspiration and biopsy. *J Clin Pathol* 2011;64:809-813.
8. Miller LJ, Philbeck TE , Montez DF, et al. Powered bone marrow biopsy procedures produce larger core specimens, with less pain, in less time than with standard manual devices. *Hematology Reports* 2011;3:e8.
9. Berenson JR, Yellin O, Blumenstein B, et al. Using a powered bone marrow biopsy system results in shorter procedures, causes less residual pain to adult patients, and yields larger specimens. *Diagnostic Pathology* 2011;6:23.
10. Reed LJ, Raghupathy R, Strakhan M et al. The OnControl bone marrow biopsy technique is superior to the standard manual technique for hematologists-in-training: a prospective, randomized comparison. *Hematology Reports* 2011;3(e21). doi:10.4081/hr.2011.e21
11. Garcia G, Miller LJ, Philbeck, T, Bolleter S, Montez D. Tactile feedback allows accurate insertion of a powered bone access device for vertebroplasty and bone marrow sampling procedures.*J Vasc and Interv Radiol* 2011;22(3):S86