

K141117_Supplement 002_Traditional 510(k) Vidacare LLC: EZ-IO Intraosseous Infusion System –Expanded Indication- Distal Femur

June 25, 2014

004_ 510(k) Summary (revised)
[807.92(c)]

vidacare

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SUMMARY

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

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Name of contact person: Diana Montez, BSN, RN
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Date Revised Summary was prepared: June 23, 2014
[807.92(a)(2)]:

Trade Name of the devices: EZ-IO Intraosseous Infusion System

Common or usual name: Intraosseous Infusion System

Classification name: Hypodermic single lumen needle

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

510(k) number	Trade or Proprietary or Model Name	Manufacturer
K132583	EZ-IO Intraosseous Infusion System	Vidacare Corporation

June 25, 2014

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

The EZ-IO Intraosseous Infusion System previously cleared with K132583 is designed to allow the user to insert a needle set consisting of a stylet and catheter through the cortex of the bone to a desired depth within the bone marrow to facilitate intraosseous infusion of desired fluids and medications for vascular access. All system materials are medical grade. Needle sets are single-use and composed of 304 stainless steel with polycarbonate hubs and available in 15 mm (for patients 3-39 kg); 25 mm (for patients 3 kg or over) and 45 mm (for patients 40 kg or over) lengths. Black lines on the needle set catheter serve as depth markers. The reusable cordless driver/drill is powered by lithium batteries with a battery-power indicator light.

Clinicians locate anatomical landmarks and clean the insertion site. Using the cordless driver with needle set attached, the needle set is pressed through the soft tissue to the outer cortex of the bone. Depth markers on the catheter must be visible prior to powering driver to ensure adequate needle length for proper placement within the medullary space. Clinicians then squeeze the driver trigger and apply moderate, steady pressure. Trigger is released when a sudden “give” or “pop” is felt, which indicates entry into the medullary space; the needle set will not always be inserted to the hub. After insertion of the needle set, the driver unit is detached from the needle set, leaving the stylet and catheter firmly seated in the bone. The stylet is then separated and removed from the catheter by turning the stylet hub counter clockwise leaving a standard Luer lock catheter securely seated in the bone. The catheter Luer lock permits attachment of standard syringes and IV tubing for administration of medications and fluids.

This submission requests the addition of the distal femur as an insertion site for the pediatric population utilizing the same insertion technique and devices previously cleared via 510(k) K132538, which includes the insertion sites of the proximal tibia, distal tibia and proximal humerus.

Proposed Expanded Indication Discussion:

Reason for requested expanded indication: To increase the usefulness of the EZ-IO with additional intraosseous insertion site options we are requesting clearance to use the distal femur as an intraosseous vascular access insertion site for the pediatric population. This will provide clinicians with another option to choose the best insertion site based on patient specific parameters such as age, anatomy, disease state, clinical situation and the clinician's experience and training. This could possibly improve patient outcomes. Just as clinicians choose which vein to use in each case where vascular access is needed, upon clearance of the distal femur clinicians would have another intraosseous site option available based on each unique patient situation.

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Overview: Anatomically and physiologically any bone that has a medullary cavity can be used to safely infuse drugs and fluids through transverse emissary veins into the central circulation. Historically, many long and several flat bones have been successfully used as an intraosseous conduit for vascular access including the distal femur, medial proximal tibia, sternum, distal tibia, clavicle, proximal humerus, olecranon, calcaneus, as well as the iliac crest.¹⁻³ The femur has been utilized as an intraosseous insertion site since 1941.⁴

Safety and Efficacy Considerations: The FDA cleared the EZ-IO intraosseous infusion device for use in 2004; initially for adults in the proximal tibia and later in pediatrics and the additional sites of the proximal humerus (humeral head), and the distal tibia. Safety considerations, in general, are concerned with potential adverse complications. The EZ-IO intraosseous device has been cleared for pediatric insertion to the femur in the European Union since 2011, and is now cleared in 39 countries outside of the United States. Vidacare has not received any reports of complications related to the distal femur site since CE clearance.

The distal femur target area is relatively large (measuring approximately 18 mm in width and 10 mm in height for a 2.7 kg infant) compared to the cleared sites of the proximal and distal tibia, making correct insertion easier. The landmarks (superior patella and distal femur) are easily identified. The closer proximity to the heart compared with the tibial sites provides quicker drug and fluid delivery to the central circulation.

In multiple publications describing intraosseous vascular access the distal femur IO insertion site is noted to be an option and has been used with success in pediatric patients.³⁻⁸

[807.92(b)(3)]:

In consideration of our cadaveric studies, preclinical vascular flow studies and Vidacare's experience with the EZ-IO Intraosseous Infusion System we conclude that use of the distal femur as an IO insertion site is safe and effective. The only change to the Indications for Use is the addition of the distal femur site.

The only change to the labeling in the proposed Directions for Use would be the additional technique for locating the anatomical landmarks for the distal femur and further detail to the general insertion instructions.

[807.92(a)(5)]:

(Proposed) Indications for Use:

The EZ-IO Intraosseous Infusion System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or

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impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

[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 K132583 and therefore, the comparison of technological characteristics listed below are identical:

Target Population
Driver Design Features
Needle Design
Technique
Sterility
Biocompatibility
Where Device is Used

References:

1. Luck R, Haines C, Mull C. Intraosseous access. *Am J Emerg Med* 2010;29:468-75.
2. Vizcarra C, Clum S. Intraosseous route as an alternative access for infusion therapy. *J Infus Nurs* 2010;33:1533-58.
3. Nagler J, Krauss B. Intraosseous catheter placement in children. *NEJM* 2011; 364(8):e14-8
4. Tocantins L, O'Neill J. Infusions of blood and other fluids into the general circulation via the bone marrow. *Surgery, Gynecology and Obstetrics* 1941;73:281-7.
5. Paxton JH. Intraosseous vascular access: A review. *Trauma* 2012;14(3):195-232.
DOI:10.1177/1460408611430175
6. Rose EC. The evidence-based use of intraosseous lines in pediatric patients. *Pediatric Emergency Medicine Practice* 2012;9(6):1-12. www.edmedicine.net
7. Barata I. Lecture Notes: "Vascular Access and Treatment of Shock in Children". American Academy of Pediatrics: Advanced Pediatric Emergency Medicine Assembly. 17March2014. PDF Notes Available at:
http://www.acep.org/uploadedFiles/ACEP/MeetingSites/PEM/Educational_Programs/MO-02%20Barata_Vascular%20Access%20and%20Shock.pdf (Accessed 06/23/2014)
8. Byars DV, Tsuchitani SN, Yates J, Knapp B. A multijurisdictional experience with the EZ-IO intraosseous device in the prehospital setting. *Am J Emerg Med* 2013.31:1712.
<http://dx.doi.org/10.1016/j.ajem.2013.08.056>



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

July 8, 2014

Vidacare LLC
Diana Montez, BSN, RN
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4350 Lockhill Selma Road
Shavano Park, TX 78249

Re: K141117
Trade/Device Name: EZ-IO Intraosseous Infusion System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: LMI
Dated: May 2, 2014
Received: May 5, 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" (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 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K141117

Device Name
EZ-IO Intraosseous Infusion System

Indications for Use (Describe)

The EZ-IO Intraosseous Infusion System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adults and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

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)

Digitally signed by Richard C. Chapman -S
Date: 2014.07.08 10:56:58 -04'00'

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