K070759

5. 510(k) Summary

vidacare®

722 Isom Road
San Antonio, TX 78216
210-375-8500

SUMMARY

MAY 21 2007

Submitter's name: Vidacare Corporation
Address: 722 Isom Road
San Antonio, TX 78216
Phone: 210-375-8500
Fax number: 210-375-8537

Name of contact person: Grace Holland
Regulatory Specialists, Inc
3722 Ave. Sausalito
Irvine, CA 92606
Phone: 949-262-0411
Fax: 949-552-2821
Email: grace@regulatoryspecialists.com

Date the summary was prepared: March 16, 2007

Name of the device: Powered EZ-IO® Pediatric Bone Marrow Aspiration System
Trade or proprietary name: Bone Marrow Aspiration System
Common or usual name: Aspiration Needle
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*
1	K062833	1	Powered EZ-IO® Bone Marrow Aspiration System	1	Vidacare Corp.
2	K051506	2	MIELO-CAN®	2	Sterylab
3	K032885	3	VidaPort Intraosseous Infusion System (Powered Adult IO)	3	Vidacare Corp.
4	K51992	4	Powered Pediatric IO (PD-IO)	4	Vidacare Corp.

Description of the device:

The Powered EZ-IO® Pediatric Bone Marrow Aspiration System consists of a reusable battery powered driver [previously cleared for aspiration in adults via 510(k) K062833], and a 25mm intraosseous (IO) device [cleared under 510(k) K032885] connected to a disposable, single use intraosseous aspiration needle set assembly. Upon activation, the drill assists the operator with needle set insertion into the bone. The driver is then separated from the hub of the needle set assembly, leaving the needle set securely seated in the bone. The trocar/stylet is then removed from the needle set leaving the 15 gauge catheter. A standard Luer lock (part of the catheter hub) then permits attachment of standard syringe for aspirating bone marrow samples. The needle set is 25mm in length [previously cleared for IO use in adults via 510(k] number K032885). This submission does not include new devices; it only requests new indications for use of the 510(k) device listed above as an aspiration product for pediatric applications.

Indications:

For Bone Marrow Aspiration of the Iliac Crest in pediatric patients.

Summary of the technological characteristics of our device compared to the predicate device:

The predicates and the Powered EZ-IO® Pediatric Bone Marrow Aspiration System were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Indications for Use
Target Population
Driver Design Features
Needle Design
Technique
Sterility
Biocompatibility
Anatomical Sites
Where Used

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vidacare Corporation
% Regulatory Specialist, Inc.
Ms. Grace Holland
Regulatory Specialist
3722 Avenue Sausalito
Irvine, California 92606

MAY 2 1 2007

Re: K070759
Trade/Device Name: Powered EZ-IO® Pediatric Bone Marrow Aspiration System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCF
Dated: May 10, 2007
Received: May 14, 2007

Dear Ms. Holland:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

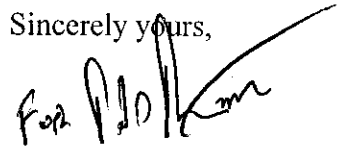
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Powered EZ-IO® Pediatric Bone Marrow Aspiration System

Indications for Use:

For Bone Marrow Aspiration of the Iliac Crest in pediatric patients.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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