5. 510(k) Summary

NOV 30 2006

VIDACARE™

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

SUMMARY

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

Date the summary was prepared: September 7, 2006

Name of the device:	Powered EZ-IO 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	K032885	1	VidaPort Intraosseous Infusion System	1	VidaCare Corp.
2	K980196	2	Manan Biopsy Set for Bone and bone Marrow	2	Medical Device Technologies, Inc.

Description of the device:

The Powered EZ-IO Bone Marrow Aspiration System consists of a reusable battery powered driver connected to a disposable intraosseous (IO) needle assembly. Upon activation, the drill penetrates through the cortex of the bone to a desired depth within the bone marrow. The driver then is separated from the hub of the IO needle assembly, leaving the cannula securely seated in the bone. The trocar/stylet containing the drill bit is then removed. A standard Luer lock (part of the needle assembly) then permits attachment of standard syringe for aspiration. The needle is 15 gauge and 60mm long.

Indications:

For Bone Marrow Aspiration of the Iliac Crest.

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

The predicates and the Powered EZ-IO 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 Specialists, Inc.
Ms. Grace Holland
Regulatory Specialist
3722 Avenue Sausalito
Irvine, California 92606

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Re: K062833
Trade/Device Name: Powered EZ-IO Bone Marrow Aspiration System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCF
Dated: October 20, 2006
Received: October 26, 2006

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.

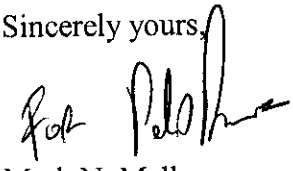
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Bone Marrow Aspiration System

Indications for Use:

For Bone Marrow Aspiration of the Iliac Crest.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____ (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

510(k) Number K062833