5. 510(k) Summary

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SUMMARY

JUL 27 2010

Submitter's name: Vidacare Corporation
Address: 4350 Lockhill Selma Road
Shavano Park, TX 78249
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: April 9, 2010

Name of the devices: Powered PD-IO Intraosseous Infusion System; EZ-IO Humeral Head; Powered PD-IO.

Common or usual name: Intraosseous Infusion System
Classification name: Hypodermic single lumen needle
Class: Class II
CFR Reference number: 880.5570
Product Code: FMI

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	K051992	1	Powered PD-IO Infusion System	1	Vidacare Corp.
2	K052408	2	EZ-IO Humeral Head	2	Vidacare Corp.
3	K063142	3	Powered PD-IO	3	Vidacare Corp.
4	K091140	4	Vidaport Intraosseous Infusion System (formerly K032885); EZ-IO Humeral Head (formerly K052408; EZ-MIO, EZ-IO, Distal Tibia (formerly K062956).	4	Vidacare Corp.

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

This submission seeks to extend the indications for use for the Powered PD-IO Intraosseous Infusion System (K051992); EZ-IO Humeral Head (K052408) and Powered PD-IO (K063142) for emergent, urgent and medically necessary intraosseous vascular access for the delivery of drugs and fluids to pediatric patients. Vidacare manufactures all of these products. The expansion of indications for these products 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 510(k) K051992, K052408, K063142 and therefore the comparison of technological characteristics listed below are identical.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Vidacare Corporation
C/O Ms. Grace Holland
Regulatory Specialist, Incorporated
3722 Ave. Sausalito
Irvine, California 92606

JUL 27 2010

Re: K101026
Trade/Device Name: Powered PD-IO Intraosseous Infusion System; EZ-IO Humeral Head; Powered PD-IO
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 9, 2010
Received: July 13, 2010

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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental 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): K101026

Device Name: The Powered PD-IO

The Powered PD-IO provides intraosseous access in the distal tibia of pediatric patients as an alternative to IV access in emergent, urgent, or medically necessary cases for up to 24 hours.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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7/28/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101026

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: EZ–IO Humeral Head

The Humeral Head EZ-IO provides vascular access when standard venous access is not possible. Humeral head IO access is indicated in pediatrics in emergent, urgent, or medically necessary cases when intravenous access is difficult or impossible to obtain for up to 24 hours.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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7/28/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

K101026

4. Indications for Use Statement

Indications for Use

JUL 27 2010

510(k) Number (if known): _____

Device Name: Powered PD-IO Intraosseous Infusion System

The Powered PD-IO Intraosseous Infusion System provides intraosseous access in the proximal tibia as an alternative to IV access in emergent, urgent, or medically necessary cases for up to 24 hours.The device is for use in pediatric patients (approximate weight range: 3kg-39kg).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Richard C. Chapman 7/27/10

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Infection Control, Dental Devices

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