FEB 18 2005

SUMMARY

Submitter's name: Address:	VidaCare Corporation 722-A Isom Road San Antonio, TX 78216
Phone: Fax number:	210-375-8500 210-375-8537
Name of contact person:	Greg Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821
Date the summary was prepared:	December 16, 2004
Name of the device:	PD-IO, Disposable Intraosseous Infusion Needle and Handle
Trade or proprietary name:	PD-IO, Disposable Intraosseous Infusion Needle and Handle
Common or usual name:	Intraosseous Infusion Needle
Classification name:	Hypodermic single lumen needle

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

VidaCare Corporation, EZ-IO* Intraosseous Infusion System, K032885
Cook, Inc., Disposable Intraosseous Infusion Needles, K913258
WaisMed BIG for Pediatrics, K022415

Description of the device:

The PD-IO Disposable Intraosseous Infusion Needle and Handle consists of a sterile single use handle with trocar and a sterile disposable single use intraosseous (IO) catheter with standard Luer lock. During use, the PD-IO needle is manually inserted through the cortex of the bone to a desired depth within the bone marrow. The insertion handle with trocar is then separated from the hub of the catheter by turning the handle counter clockwise and then removed

K063494

leaving the catheter securely seated in the bone. The catheter has a standard Luer lock that permits attachment of standard syringes and IV tubing for administration of drugs and fluids.

Indications for Use:

The PD-IO Disposable Intraosseous Infusion Needle and Handle provides intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients.

Summary of the technological characteristics of the VidaCare PD-IO Disposable Intraosseous Infusion Needle and Handle compared to the predicate devices:

The predicate Cook, Disposable Intraosseous Infusion Needles K913258, VidaCare Corporation EZ-IO K032885 and the WaisMed Ltd BIG Pediatric K022415 were compared in the following areas and found to have similar technological characteristics and to be equivalent to the PD-IO Disposable Intraosseous Infusion Needle.

Indications for use
Design features
Needle design
Technique
Sterility
Biocompatibility
Anatomical site
Where used
Standards met
Target population
Mechanical safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

VidaCare Corporation
C/O Mr. Greg Holland
Regulatory Specialist
Regulatory Specialists, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

Re: K043490
Trade/Device Name: PD-IO Disposable Intraosseous Infusion Needle and Handle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 16, 2004
Received: December 17, 2004

Dear Mr. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known): K043490

Device Name: PD-IO Disposable Intraosseous Infusion Needle and Handle

Indications For Use:

The PD-IO Disposable Intraosseous Infusion Needle and Handle provides intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K043490