K051992



OCT 20 2005

VIDACARE

722-A Isom Road
San Antonio. TX 78216
210-375-8500

SUMMARY

| | |
|---|---|
| Submitter's name:<br>Address: | VidaCare Corporation<br>722-A Isom Road<br>San Antonio, TX 78216 |
| Phone:<br>Fax number: | 210-375-8500<br>210-375-8537 |
| Name of contact person: | Grace Holland<br>Regulatory Specialists, Inc<br>3722 Ave. Sausalito<br>Irvine, CA 92606<br>Phone: 949-262-0411<br>Fax: 949-552-2821 |
| Date the summary was prepared: | July 19, 2005 |
| Name of the device: | Powered PD-IO Intraosseous Infusion System |
| Trade or proprietary name: | Powered PD-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)]:

PD-IO Disposable Intraosseous Infusion Needle (K043490), manufactured by VidaCare.
VidaPort Intraosseous Infusion System (K032885), manufactured by VidaCare.

Description of the device:

The Powered PD-IO Intraosseous Infusion System (which looks similar to a cordless drill) consists of a reusable battery powered driver connected to a single use 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 separates 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 syringes and IV lines for administration of drugs and fluids.

Indications:

The Powered PD-IO Intraosseous Infusion System provides intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients, from birth to 21 years of age (approximate weight range: 3 kg - 39 kg).

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

The predicates PD-IO Disposable Intraosseous Infusion Needle (K043490), VidaPort Intraosseous Infusion System (K032885), and the Powered PD-IO Intraosseous Infusion System were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Indications for use
Target population
Drill Design
Needle Design
Technique
Performance
Sterility
Biocompatibility
Mechanical Safety
Anatomical site
Where used

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Vidacare Corporation
C/O Ms. Grace Holland
Regulatory Consultant
Regulatory Specialists, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

Re: K051992
Trade/Device Name: POWERED PD-IO INTRAOSSEOUS INFUSION SYSTEM
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: FMI
Dated: July 19, 2005
Received: July 22, 2005

Dear Ms. Holland:

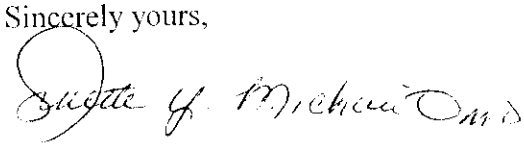
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (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

K051992



# Indications For Use Statement

510(k) Number (if known): K051992

Device Name: Powered PD-IO Intraosseous Infusion System

Indications For Use:

The Powered PD-IO Intraosseous Infusion System provides intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients, from birth to 21 years of age (approximate weight range: 3 kg - 39 kg).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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: K051992