K063142

5. 510(k) Summary

DEC - 8 2006

vidacare

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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: October 10, 2006

Name of the device: Manual PD-IO and Powered PD-IO
Trade or proprietary name: Manual PD-IO and Powered PD-IO
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)]:

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K043490	1	Manual PD-IO	1	Vidacare Corp.
2	K051992	2	Powered PD-IO	2	Vidacare Corp.
3	K913258	3	Disposable Introsseous Infusion Needles	3	Cook, Inc.

Description of the device:

The following descriptions, for the manual and powered drivers include two different drivers. The same needle set is used for both drivers.

The Manual PD-IO, previously cleared under 510(k) K043490, consists of a proprietary pentagon shaft permanently attached to an ergonomically designed handle. The manual driver is designed to allow the user to manually insert a needle set consisting of a stylet and catheter through the cortex of the bone to a desired depth within the bone marrow to facilitate the infusion of desired fluids. After insertion of the needle set into the bone, the manual driver is detached from the needle set, leaving the stylet and catheter firmly seated in the bone. The stylet is then separated and removed from the catheter by turning the stylet hub counter clockwise leaving a standard Luer lock catheter securely seated in the bone. The catheter Luer lock permits attachment of standard syringes and IV tubing for administration of drugs and fluids (not supplied). The Manual PD-IO system is approved for use in the proximal tibia under 510(k) K043490. The size needle that can be used in the distal tibia utilizing the Manual PD-IO is identical to the predicate, 15G X 15mm. This submission extends the indication for use of the manual device to include the distal tibia in pediatrics utilizing the same technique and device previously cleared for the proximal tibia via 510(k) K043490.

The Powered PD-IO, previously cleared under 510(k) K051992 for pediatric use, consists of a reusable battery powered driver connected to a single use disposable intraosseous (IO) needle assembly. Upon activation, the drill supplies power to the needle set in order to penetrate through the cortex of the bone to a desired depth within the bone marrow. After insertion of the needle set, the power driver is detached from the needle set, leaving the stylet and catheter firmly seated in the bone. The stylet is then separated and removed from the catheter by turning the stylet hub counter clockwise leaving a standard Luer lock catheter securely seated in the bone. The catheter Luer lock permits attachment of standard syringes and IV tubing for administration of drugs and fluids (not supplied). The Powered PD-IO intraosseous system is cleared for use in the proximal tibia under 510(k) K051992. The size needle that can be used with the Powered PD-IO is identical to the predicate 15G X

15mm. This submission extends the indication for use of the powered device to include the distal tibia in pediatric patients utilizing the same technique and device previously cleared for the proximal tibia via 510(k) K051992.

Indications:

The Manual PD–IO and Powered PD–IO provide intraosseous access in the distal tibia of pediatric patients as an alternative to IV access during emergencies.

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

The Manual PD-IO for Distal Tibia access has the exact same technology as the Manual PD-IO (K043490). The Powered PD-IO for Distal Tibia access has the exact same technology for use as the Powered PD-IO (K051992).

Vidacare also wishes to use as a predicate Disposable Intraosseous Infusion Needles, K913258, by Cook, Inc., as these needles have the exact same indications for use for which we are applying. These needles are used as an alternative to intravenous access during pediatric emergencies. The distal tibia is one of the access sites in their instructions for use.

This submission extends the indication for use to include the distal tibia site in pediatrics of the Manual PD-IO and the Powered PD-IO intraosseous systems. There have been no changes to the design or components of the Manual PD-IO and the Powered PD-IO intraosseous systems cleared under 510(k) K043490 and K051992 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
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2006

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

Re: K063142
Trade/Device Name: Manual PD-IO and Powered PD-IO
Regulation Number: 21 CFR 880.5570
Regulation Name: Single Lumen Hypodermic Needle
Regulatory Class: II
Product Code: FMI
Dated: October 10, 2006
Received: October 16, 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.

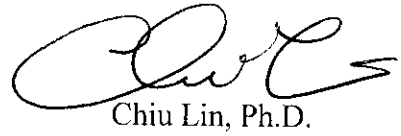
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Manual PD-IO and Powered PD-IO

The Manual PD–IO, and Powered PD–IO provide intraosseous access in the distal tibia of pediatric patients as an alternative to IV access during emergencies.

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)

for AOW 12/8/04

...ology, General Hospital,
...Control, Dental Devices

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