K062956

5. 510(k) Summary

vidacare

DEC - 5 2006

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SUMMARY

Submitter's name: Vidacare Corporation
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Name of contact person: Grace Holland
Regulatory Specialists, Inc
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Irvine, CA 92606
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Date the summary was prepared: September 28, 2006

Name of the device: EZ-MIO and EZ-IO
Trade or proprietary name: EZ-MIO and EZ-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	K052195	1	EZ-MIO Manual Driver	1	Vidacare Corp.
2	K032885	2	VidaPort Intraosseous System (powered)	2	Vidacare Corp.

Description of the device:

The EZ–MIO, manual driver, previously cleared under 510(k) K052195, 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, the manual driver is detached from the needle set, leaving the stylet and cannula 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 size needle that can be used in the distal tibia utilizing the MIO manual driver is identical to the predicate 15g X 25mm. The EZ-MIO system is approved for use in the proximal tibia under 510(k) K052195. This submission extends the indication for use of the manual device to include the distal tibia in adults utilizing the same technique and device previously cleared for the proximal tibia via 510(k) K052195.

The EZ–IO powered driver, previously cleared under 510(k) K032885 for adult 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 cannula 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 size needle that can be used with the EZ-IO powered driver is identical to the predicate 15g X 25mm. The EZ-IO powered intraosseous system is cleared for use in the proximal tibia under 510(k) K032885. This submission extends the indication for use of the powered device to include the distal tibia in adults utilizing the same technique and device previously cleared for the proximal tibia via 510(k) K032885.

Indications:

The EZ–MIO and EZ–IO intraosseous system provides intraosseous access in the distal tibia of adults as an alternative to IV access during emergencies.

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

This submission extends the indication for use to include the distal tibia site in adults of the EZ-MIO manual and the EZ-IO powered intraosseous systems. There have been no changes to the design or components of the EZ-MIO or EZ-IO cleared under 510(k) K052195 and K032885 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

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

DEC - 5 2006

Re: K062956
Trade/Device Name: EZ-MIO, EZ-IO Distal Tibia
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 28, 2006
Received: September 29, 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 (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

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: EZ-MIO and EZ-IO

The EZ-MIO manual driver and EZ-IO power driver provide intraosseous access in the distal tibia of adults as an alternative to IV access during emergencies.

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

(Sign-Off)
...n of Anesthesiology, General Hospital,
...on Control, Dental Devices

...Number: K062954

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