K052195

NOV - 2 2005

VIDACARE™

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

SUMMARY

Submitter's name:	VidaCare Corporation
Address:	722-A Isom Road San Antonio, TX 78216
Phone:	210-375-8500
Fax number:	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:	August 7, 2005
Name of the device:	MIO Reusable Manual Driver
Trade or proprietary name:	MIO Reusable Manual Driver
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)]:

Applicant	Device	510(k)
VidaCare Corporation	VidaPort Intraosseous Infusion System, *	K032885
VidaCare Corporation	PD-IO Disposable Intraosseous Infusion Needle	K043490

Description of the device:

The EZ-MIO, Manual Driver consists of a proprietary pentagon shaft permanently attached to an ergonomically designed handle. The EZ-MIO, Manual Drivers are designed to allow the user to manually insert a needle set consisting of a stylet and catheter into 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). There are two size needles that can be used with the EZ-MIO, Manual Driver, an adult size, 15g X 25mm, and pediatric size, 15g X 15mm. A more detailed description, with drawings, can be found in TAB 6 – DESCRIPTION.

Indications for Use:

The PD-IO™ infusion system provides intraosseous access in proximal tibia, as an alternative to IV access during emergencies to pediatric patients, from birth to 21 years of age (approximate weight range: 3 kg - 39 kg).

The EZ-IO™ Infusion System provides intraosseous access in the proximal tibia, as an alternative to IV access during emergencies to adult patients (22 years of age or older, > 40 kg)

Summary of the technological characteristics of the EZ-MIO, Manual Driver

The predicates were compared in the following areas and found to have similar technological characteristics and to be equivalent to the EZ-MIO, Manual Driver.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2005

Vidacare Corporation
C/O Mr. Greg Holland
Regulatory Consultant to Vidacare
Regulatory Specialists, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

Re: K052195
Trade/Device Name: EZ-MIO MANUAL DRIVER
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: FMI
Dated: August 7, 2005
Received: August 12, 2005

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

ATTACHMENT C –
Indications For Use Statement

510(k) Number (if known): K052195

Device Name: EZ-MIO Intraosseous Infusion System

Indications For Use:

For pediatric use:
The PD-IO™ infusion system provides intraosseous access in proximal tibia, as an alternative to IV access during emergencies to pediatric patients, from birth to 21 years of age (approximate weight range: 3 kg - 39 kg).

For adult use:
The EZ-IO™ Infusion System provides intraosseous access in the proximal tibia, as an alternative to IV access during emergencies to adult patients (22 years of age or older, > 40 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)

Anthony D. Watson

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

510(k) Number: K052195