K032885

MAR 1 0 2004

VidaCare Corporation

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:	March 2, 2004
Name of the device:	VidaPort Intraosseous Infusion System
Trade or proprietary name:	VidaPort Intraosseous Infusion System
Common or usual name:	Bone injection system
Classification name:	Hypodermic single lumen needle

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

K981853, Bone Injection Gun, manufactured by WaisMed Ltd.

Description of the device:

The VidaPort (which looks similar to a cordless drill) consists of a reusable battery powered driver connected to a disposable intraosseous (IO) needle assembly. Upon activation, the drill penetrates through the cortex of the bone to a preset 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 VidaPort provides intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in adult patients only. The device is prescription use only per 21 CFR 801.109.

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

The predicate Bone Injection Gun, K981853 and the VidaPort 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
Standards met

Testing:

Electrical Safety
Electrical Emissions
Mechanical
Animal
Body

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2004

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

Re: K032885
Trade/Device Name: VidaPort Intraosseous Infusion System
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 18, 2003
Received: December 19, 2003

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.

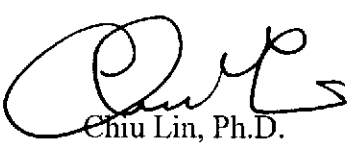
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.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

510(k) Number (if known): K032885

Device Name: VidaPort Intraosseous Infusion System

Indications For Use:

The VidaPort provides intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in adult patients only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Irene Nawaz Interim Branch Chief 3/5/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K032885