6. 510(k) Summary

JUL 10 2006

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:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821

Date the summary was prepared: June 21, 2006

Name of the device:	EZ-Connect
Trade or proprietary name:	EZ-Connect
Common or usual name:	Extension Set
Classification name:	Set, Administration, Intravascular
Class:	II
Product code:	FPA
21 CFR Reference:	880.5440

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

Applicant:	Codan US Corp
Device:	EXTENSION SET LIGHT-SAFE, MODEL BC565
510(k):	K021480

Description of the device:

The EZ-Connect is an extension set comprised of 150 mm of tubing with a right angle luer lock connector and cap on one end, a standard straight luer lock connected to a needleless connector on the other end and a pinch clamp in the middle.

Indications for Use:

The EZ-Connect Extension Set is indicated to facilitate the infusion of IV fluids from a plastic bag or solution container into the patient.

Summary of substantial equivalence:

The EZ-Connect was compared in the following areas and found to have similar technological characteristics and to be equivalent to the predicate.

Biocompatibility
Design features
Indications for use
Standards met
Sterility
Target population
Where used

Conclusion:

The EZ-Connect Extension Set meets the functional claims and intended use as described in the product labeling, and is as safe and effective in terms of substantial equivalence as the predicate Codan Extension Set Light-Safe Model BC 565.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2006

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

Re: K061771
Trade/Device Name: EZ-Connect
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 21, 2006
Received: June 26, 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.

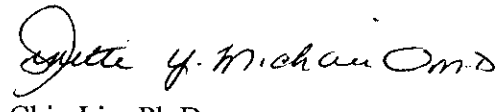
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

5. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: EZ-Connect
Indications for Use:

The EZ-Connect is indicated to facilitate the infusion of IV fluids from a plastic bag or solution container into the patient.

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)

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number: K061771