510(k) Summary for DANA Diabecare® IIS

SPONSOR
SOOIL Development Co, Ltd.
196-1, Dogok-dong, Kangnam-gu
Seoul 135-270
Korea

FEB - 2 2007

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Date of Preparation: October 13, 2006

DEVICE NAME

Proprietary Name:	DANA Diabecare® IIS
Common/Usual Name:	Insulin Infusion pump
Classification Name:	Infusion pump
Class Type:	Class II

PREDICATE DEVICE

DANA Diabecare® II Insulin Pump (SOOIL Development Co., Ltd., K022317, cleared for marketing August 2, 2002).

DEVICE DESCRIPTION

The DANA Diabecare® IIS insulin pump is a modification of the device described in K022317, the DANA Diabecare® II Insulin Pump.

The DANA Diabecare® IIS insulin pump is a digitally controlled syringe pump that provides precise insulin delivery and monitoring of device functions. The DANA Diabecare® IIS insulin pump has two insulin delivery modes, the basal infusion rate and meal bolus injections. The user can program up to 24 basal infusion dosages in one-hour increments and three bolus injections daily. The basal infusion rate can be temporarily increased or reduced to accommodate changes in activity levels.

The DANA Diabecare® IIS insulin pump is battery powered, water resistant, compact, and lightweight. The pump is equipped with safety systems, acoustic signals, and an

LCD display that reads "SE" for a system error. The data that can be stored and retrieved from the DANA Diabecare® IIS insulin pump software includes the following: 100 alarms, 500 bolus doses, 500 daily insulin dosages, and 500 prime histories. The pump also has an error log.

DANA Diabecare® IIS is intended to be used with a proprietary insulin reservoir and the infusion set. The insulin reservoir is a 3mL plastic syringe with a 300-unit insulin capacity. Accessories for the device include the SUPERLINE, SUPERLINE-Easy Release, Soft-Release-R and Soft-Release-ST, which are identical to those included with the DANA Diabecare® II Insulin Pump, and consist of a 55cm/(70cm)/110cm length of tubing with a luer-lock connector on the proximal end for attachment to the insulin syringe and a 27G needle on the distal end. Additional accessories necessary for operation and maintenance of the pump, syringe, and infusion set are provided with the DANA Diabecare® IIS pump.

INTENDED USE

The DANA Diabecare® IIS is an external programmable syringe infusion pump used for the subcutaneous delivery of insulin for the treatment of diabetes mellitus. The pump is not intended for use with blood or blood products.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The modifications made to the predicate DANA Diabecare® II insulin pump to create the proposed DANA Diabecare® IIS insulin pump were implemented to enhance the convenience and ease of use of the device. The modifications were limited to software modifications, including changes to the insulin delivery modes and information storage feature, and one minor change in the material used for the microcontroller of the Main Program. In addition, a carbohydrate counting bolus calculator, a button scroll, and a display language setting were added, and the proposed DANA Diabecare® IIS allows for automatic configuration of insulin dosage, extended meal bolus delivery, and dual pattern bolus delivery.

PERFORMANCE TESTING

Module and system verification and validation testing was performed on the modified software for the DANA Diabecare® IIS insulin pump. The verification and validation testing confirmed that all new and modified subroutines performed as designed and conformed to the software requirement specifications. The modified software is safe and effective for controlling and monitoring the operation of the DANA Diabecare® IIS insulin pump. A risk analysis was also performed in accordance with the requirements of Medical Device Directive 93/42/EEC and ISO 14971 which confirmed that the modified DANA Diabecare® IIS insulin pump is safe and effective for its intended use for the subcutaneous delivery of insulin for the treatment of diabetes mellitus

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sooil Development Company, Limited
C/O Mr. Jeremy Kim
Sooil, LLC
5677 Oberlin Drive, Suite 101
San Diego, California 92121

FEB - 2 2007

Re: K063126
Trade/Device Name: DANA Diabecare™ IIS Insulin Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: January 24, 2007
Received: January 24, 2007

Dear Mr. Kim:

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.

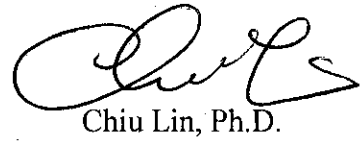
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Enclosure

Indications for Use Statement

510(k) Number (if known): K063126

Device Name: DANA Diabecare® IIS Insulin Pump

Indications for Use:

The DANA Diabecare® IIS insulin pump is an external digitally controlled syringe pump that is intended for the subcutaneous delivery of insulin for the treatment of diabetes mellitus. It is not intended for use with blood or blood products.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible], General [illegible]
[illegible] Devices

K063126