K082512

510(k) Executive Summary

August 20, 2008

NOV - 7 2008

Company Name: Dimensional Dosing Systems

Company Address: 2465 Dogwood Drive
Wexford, PA 15090

Telephone: (724) 933-7874

Contact Person: John McMichael

Summary Preparation Date: September 4, 2007

Trade Name: *My Insulin Doser/IDS*

Common Name: Dosing Calculator

Classification Name: Calculator, Drug Dose

Predicate Device Identification:
CFR21 868.1890
Dosing Calculator
Product Code: NDC
Device Class: II

LEGALLY MARKETED EQUIVALENT DEVICE

Company	***Product***	***510(k) #***
RxFiles	TRxF Intelligent Dosing System	K011571

DESCRIPTION OF DEVICE

My Insulin Doser/IDS is a next dose calculator for any insulin that can be used by patients with a prescription from a licensed prescriber.

INTENDED USE OF THE DEVICE

My Insulin Doser/IDS allows a diabetic patient to calculate the best next dose of insulin to achieve a personal glucose target.

TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE AS COMPARED TO PREDICATE DEVICE [

Predicate Product Comparison Table:

Manufacturer	**Dimensional Dosing Systems**	**Dimensional Dosing Systems**
Trade Name	*"My Insulin Doser/IDS"*	TRxF Intelligent Dosing System (IDS)
K Number		K011571
Intended Use	*My Insulin Doser/IDS* allows a diabetic patient to calculate the best next dose of insulin to achieve a personal glucose target.	Software based drug dosing calculator designed for use by the physician to calculate next dose of any drug to achieve a desired target
Device Description	My Insulin Doser/IDS a next dose calculator for any insulin that can be user by patients with a prescription from a licensed prescriber.	The IDS™ is a "next" dose calculator for any drug that can be used by physicians to calculate the next dose for patients.
Target population	Diabetic Patient	Healthcare professional
Where used	Home	Healthcare facility
Human Factors	Patient enters their own glucose values and amounts of insulin taken. Warnings are presented when values are out of range and/or insulin doses are < or > 20% of the most recent dose.	Physicians enter patient's glucose values and amounts of insulin. Warnings are presented when values are out of range and/or insulin doses are < or > 20% of the most recent dose.
Performance	Performance testing was performed and all tests showed satisfactory results.	Performance testing was performed and all tests showed satisfactory results.
Software based	Yes	Yes
Dose calculation	Yes	Yes

Discussion of Similarities and Differences with the Predicate Product:

The Intelligent Dosing System (IDS) for Physicians was chosen as a substantially equivalent device. *My Insulin Doser/IDS* has the following similarities to those of the predicate device:

- Uses the same algorithm
- Uses the same operating principles
- Uses a similar graphical user interface.
- Available via the Palm, PC or Website.
- User enters same variables.

The only modifications made are:

- Single Patient only
- Insulin only

Conclusion:

My Insulin Doser/IDS is identical to the predicate device in functionality except for a few features that allow the device to be a single patient dosing calculator devised for insulin dosing only. The predicate device, the Intelligent Dosing System IDS) was developed as a dosing calculator for the healthcare professional and was approved for all drugs, including insulin. The IDS for Insulin takes the same software and technology and is a dosing calculator developed for a single patient and single drug. This device allows the patient to participate in insulin dosing, but has the added benefit of a remote patient management that allows the healthcare professional to view patient data anytime from anywhere with internet access

My Insulin Doser/IDS uses the same fundamental technology features as the Intelligent Dosing System and delivers the same level of effectiveness. Therefore, it is concluded that there is no significant difference in the basic function, safety and effectiveness between the Intelligent Dosing System (Predicate Device) and *My Insulin Doser/IDS*.

NON-CLINICAL PERFORMANCE DATA AND CONCLUSIONS FROM NON-CLINICAL TESTS

Labeling Comprehension study for 55 patient users to implement and understand My Insuiln Doser system. The system was designed around a 6^{th} grade reading comprehension level. Subjects ranged in age from 18-80 years old.

Subjects were given My Insulin Doser/IDS users manual to read as well as given a demonstration of the software on any of the 3 platforms (PALM, PC and WEB),

CLINICAL PERFORMANCE DATA AND CONCLUSIONS FROM CLINICAL TESTS

The study was a Phase IV in which nursing home residents who were maintained on two or more OADs were converted to an insulin replacement algorithm. The insulin titration algorithm developed by Dimensional Dosing Systems, Inc. was employed to help stabilize blood glucose following conversion from OAD therapy.

SOFTWARE INFORMATION

Software Documentation	Concern
Level of Concern	Major
Software Description	Provided
Device Hazard Analysis	Provided
Software Requirements Specifications	Provided
Architecture Design Chart	Provided
Software Design Specifications	Provided
Traceability Analysis	Provided
Software Development Environment Description	Provided
Verification and Validation Documents	Provided
Revision Level History	Provided
Unresolved Anomalies (Bugs or Defects)	Provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dimensional Dosing Systems
C/O Mr. E.J. Smith
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K082512
Trade/Device Name: My Insulin Doser/IDS
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: NDC
Dated: August 29, 2008
Received: August 29, 2008

Dear Mr.Smith:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Angelie G. Michaud MD
FOR DR CHIU LIN

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number:

Device Name: *My Insulin Doser/IDS*

Intended Use Statement:

My Insulin Doser/IDS allows a diabetic patient to calculate the best next dose of insulin to achieve a personal glucose target.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K982512