 <b>WELLDOC</b> <sup>®</sup>	TITLE: Response to FDA Feedback on 510 (K) K100066	
	7/9/2010	

### 510(k) Summary

**General Information:**

**JUL 15 2010**

Date of Summary Preparation: June 10, 2010

Name and Address of Manufacturer: WellDoc, Inc.  
1501 St Paul Street, Suite 118  
Baltimore, MD 21217

Contact Person: Ryan Sysko  
Chief Executive Officer  
Telephone (443) 692-3101  
Fax (444) 269-0272

Trade Names: DiabetesManager<sup>®</sup> System  
DiabetesManager<sup>®</sup>-Rx System

Common Names: Medical computers and software  
Infusion pump accessories

Regulation Numbers: LNX is unclassified and therefore has no regulation number  
  
21 CFR 880.5725 (Infusion Pump)


Classification Names: Medical computers and software  
  
Infusion pump

Regulatory Class: II

Classification Panel: General Hospital

Product Codes: LNX  
MRZ

Predicate Devices: K043529 ACCU-CHEK<sup>®</sup>-Advisor  
Insulin Guidance Software  
  
K080227 ACCU-CHEK<sup>®</sup>-360<sup>°</sup> Diabetes  
Management System

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**Indications for Use:**

**DiabetesManager® (OTC Use):** The WellDoc DiabetesManager® System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older – who have type 2 diabetes. The DiabetesManager® System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager® System analyzes and reports blood glucose test results and supports medication adherence. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

**DiabetesManager®-Rx (Prescription Use):** The WellDoc DiabetesManager®-Rx System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older – who have type 2 diabetes. The DiabetesManager®-Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager®-Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the DiabetesManager®-Rx System provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.


The DiabetesManager®-Rx System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

**Device Description:**

The DiabetesManager System (Version 1.1) is a stand-alone, over-the-counter (OTC) software system that has the capability of providing additional functions, if and when, the functions are prescribed by the prescribing healthcare provider. Once the additional prescription (Rx) functions are activated, the entire software system is called DiabetesManager-Rx® System (Version 1.1).

Both DiabetesManager System and DiabetesManager-Rx System are implemented through an enterprise such as a health plan or large physician group in tandem with healthcare providers (HCPs) and are comprised of a Mobile application (patient only) and Web-based applications for the patient, account director (AD), and healthcare provider(s). The applications are called:

- Account Director Web-Based Application
- Patient Mobile Based Application
- Patient Web-Based Application
- HCP Web-based Application

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The Account Director application is used for administrative purposes. The HCP application is used by healthcare providers to review patient entered data and the prescribing healthcare provider can activate the Rx system for the patient.

### **Patient Applications**

The Patient Web-based application and the Patient Mobile application have a similar feature set. Data entered into these applications is stored in the database and can be retrieved for display in either application. Both applications require the initial web-based registration before the patient can access them. Patients are identified by healthcare providers and invitations to register are sent by Account Directors.

On the patient applications (Mobile and Web-based), the basic DiabetesManager System functions as an information repository (logbook and Personal Health Record-PHR), diabetes education resource (learning library and health tips), and secure communication system (Message Center). If and when a prescription is obtained, additional functions become available to the patient as DiabetesManager-Rx System. Prescription functions include additional medication information (dose and schedule), coaching (BG real-time coaching feedback), messaging (Message Center Content), and workflow and decision support for healthcare providers.

### **Performance Data:**

Human factors study results and software verification and validation (documented in accordance with FDA’s “Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”) were provided and supported substantial equivalence.

### **Substantial Equivalence:**

The DiabetesManager and DiabetesManager-Rx include indications for use that are similar to and consistent with those of the predicate devices, do not impact safety or effectiveness, and have the same intended uses as the predicate devices. Additionally, the DiabetesManager and DiabetesManager-Rx’s technological characteristics are similar to and consistent with those of the predicate devices, e.g., all include software applications that provide data capture, storage, transmission, analysis and reporting of blood glucose (BG) values; all have data analysis and review features that provide BG trends and statistics; the DiabetesManager, DiabetesManager-Rx and ACCU-CHEK<sup>®</sup> 360° identify, analyze and display in- and out-of- target BG and historical lab values. Additionally, the ACCU-CHEK<sup>®</sup> Advisor provides directions which are similar to directions that physicians provide to patients as part of routine clinical practice. Likewise, the self management messages in the DiabetesManager and the blood glucose feedback and trend messages in the DiabetesManager-Rx are similar to directions that physicians provide to patients as part of routine clinical practice and are based on evidence-based standards of care. Minor technological differences do not impact safety or effectiveness as compared to the predicate devices. Therefore, DiabetesManager and DiabetesManager-Rx are substantially equivalent.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room –WO66-G609  
Silver Spring, MD 20993-0002

Mr. Ryan Sysko  
Chief Executive Officer  
WellDoc, Incorporated  
1501 Saint Paul Street, Suite 118  
Baltimore, Maryland 21202

JUL 15 2010

Re: K100066  
Trade/Device Name: WellDoc DiabetesManager<sup>®</sup> System and DiabetesManager<sup>®</sup> Rx System  
Regulation Number: 21 CFR 880.5725  
Regulation Name: Infusion Pump  
Regulatory Class: II  
Product Code: MRZ , LNX  
Dated: June 14, 2010  
Received: June 15, 2010

Dear Mr. Sysko:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.


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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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**Attachment A: Revised Indications for Use**

**Indications for Use**

510(k) Number (if known): \_\_\_\_\_

Device Name: WellDoc DiabetesManager<sup>®</sup> System and DiabetesManager<sup>®</sup> -Rx System

Indications for Use:

**DiabetesManager (OTC Use):**

The WellDoc DiabetesManager<sup>®</sup> System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older – who have type 2 diabetes. The DiabetesManager System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager System analyzes and reports blood glucose test results and supports medication adherence. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

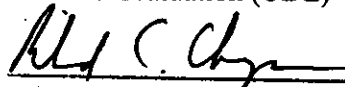
**DiabetesManager-Rx (Prescription Use):**

The WellDoc DiabetesManager -Rx System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older – who have type 2 diabetes. The DiabetesManager-Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager -Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the DiabetesManager -Rx System provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information. The DiabetesManager-Rx System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Prescription Use   X   AND/OR Over-The-Counter Use   X    
(Part 21 CFR 801 Subpart D) (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)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K100066