WellDoc, Incorporated
Lauren Bronich-Hall
Director, Quality System
1501 Saint Paul Street, Suite 118
Baltimore, Maryland 21202

May 17, 2024

Re: K112370
Trade/Device Name: WellDoc DiabetesManager® System and DiabetesManager®-Rx System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: MRZ

Dear Lauren Bronich-Hall:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 14, 2011. Specifically, FDA is updating this SE letter as an administrative correction. A second product code was inadvertently included.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Juliane Lessard, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 240-402-6126, Juliane.Lessard@fda.hhs.gov.

Sincerely,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery,
General Hospital and Human Factors Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Lauren Bronich-Hall
Director, Quality System
WellDoc Incorporated
1501 Saint Paul Street, Suite 118
Baltimore, Maryland 21202

OCT 14 2011

Re: K112370
Trade/Device Name: WellDoc DiabetesManager® System and DiabetesManager®-Rx System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, LNX
Dated: September 19, 2011
Received: September 21, 2011

Dear Ms. Bronich-Hall:

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

Indications for Use

510(k) Number (if known): K112370

Device Name: WellDoc DiabetesManager® System and DiabetesManager®-Rx

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/3/4

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

510(k) Number: K112370

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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/13/6

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

510(k) Number: K112370