Abbott Diabetes Care Inc.
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K123089

APR 0 5 2013

510(k) Summary

According to the requirements of 21 CFR §807.92, the following information provides detail for a determination

General Information

Submitter Information	Abbott Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502
Contact Person:	David Lambert Senior Regulatory Affairs Specialist
Telephone No.	510-749-5105
Fax No.	510 864-4791
Date Prepared	February 1, 2013
Device Information:	
Proprietary Name:	Freestyle Auto-Assist Software Version 2.0
Common Name:	i) System, Test, Blood Glucose, Over the counter, ii) Calculator/data processing module, for clinical use
Classification Name	i) Glucose test system. (21 CFR 862.1345, Product Code NBW) ii) Calculator/data processing module, for clinical use. (21 CFR 862.2100, Product Code JQP)
Predicate Device:	CoPilot™ Health Management System Cleared under K062770
Legal Manufacturer:	Abbott Diabetes Care Ltd Range Road Witney Oxon OX29 0YL UK

Indication For Use

The Freestyle Auto-Assist Software Version 2.0 is intended for use by people with diabetes to aid in the review, analysis and evaluation of information such as blood glucose results, blood ketone test results and other data uploaded from a compatible meter, such as insulin doses and exercise data from the Freestyle Insulinx meter, in support of an effective diabetes health management program.

Freestyle Auto-Assist software is not intended for the diagnosis of or screening for diabetes mellitus.

Device Description and Technological Characteristics

Freestyle Auto-Assist Software Version 2.0 is a software application that allows people with diabetes to upload data from Freestyle Insulinx, Precision Xtra™, Freestyle Freedom, Freestyle 5, Freestyle Flash, Freestyle Lite and Freestyle Freedom Lite Blood Glucose Monitoring Systems into FreeStyle Auto-Assist Software Version 2.0, where users may review blood glucose and other data in a number of different graphical presentations.

It is a stand-alone software program available for download to a home user's computer via download from an Abbott Diabetes Care (ADC) website or if a previous version of Auto-Assist software is installed on the computer, through a notification from the ADC Informatics Upgrade Server. The software will also be available to users via a CD-ROM.

FreeStyle Auto-Assist Software Version 2.0 is intended for use in home settings by lay users to upload data from compatible meters to a patient's computer. Users can use FreeStyle Auto-Assist Software Version 2.0 to upload glucose data and other information (user entered notes, sound notifications, reminders) from their glucose meter and manually enter personal notes, such as insulin, meals, and exercise data. The software provides graphs and other software tools to help organize and present glucose readings, insulin dosage, and other diabetes-related factors that have been uploaded from devices or manually entered.

FreeStyle Auto-Assist Software Version 2.0 organizes the data in a presentable manner that is easy to view and interact with (save, generate reports and print reports). Communication with the devices is achieved through a serial cable or serial/USB adapter cable.

The following functions are supported by FreeStyle Auto-Assist Software Version 2.0:

- **Data Upload**
  FreeStyle Auto-Assist Software Version 2.0 retrieves each blood glucose test result or ketone result, and the date and time of the measurement, from the memory of recognized, compatible meters. It retrieves the data through either a

Serial or Serial/USB cable, a Strip Port /USB cable, or a Micro-USB/USB cable. These data are viewable through and used by FreeStyle Auto-Assist Software Version 2.0 to generate reports. Additionally these data may be exported to a text file (.txt) and saved.

- **Data Entry**
  Through the FreeStyle Auto-Assist Software Version 2.0 user interface additional personal notes, such as insulin, meals, and exercise data may be added to the logged data collected from the meter.
- **Data Access**
  Data from the compatible meter can be displayed through the software or saved in text file format (.txt).
- **Meter Settings Backup**
  For compatible meters, the meter settings listed in the table below are retrieved from the meter. The meter settings can be saved to the computer by selecting the backup meter file option.

Table 1. Meter Settings

Setting
Patient Name
Patient ID
Date/Time
Clock Mode
Button Sound
Sound Notifications
Notes
Reminders (Alarms)
Weekly Messages
Personalization Image
Insulin units (manual entry 1 or ½ unit)

- **Report Generation**
  For compatible meters, the following reports are available:

Table 2. Auto-Assist 2.0 System Reports

Report Type	Description
Snapshot	General summary of data for the specified date range. It also includes notes that inform the patient and their healthcare professional about important trends in blood glucose data by putting the data into words
Modal Day	Shows the daily pattern of glucose levels over the specified date range.

Table 2. Auto-Assist 2.0 System Reports

Report Type	Description
Logbook	Displays a table of glucose, carbohydrate, and insulin values associated with each time period over the specified date range.
Glucose Average	Separates all glucose readings over the specified date range into pre-meal and post-meal groupings and averages the values for each group.
Daily Statistics	Provides an overview of blood glucose, and other values such as ketones and insulin, over the date range if supported by your meter.
Meal Event Averages (Compatible meters only)	Compares the before-meal and after-meal blood glucose levels for the morning, midday and evening over the specified date range. This report also shows before and after meal averages, and insulin and carbohydrate intake for meals.

- **Report Printout**
  Once generated, reports can be printed through an available printer or saved to the computer in portable document file (.pdf) format.

- **Date/Time Synchronization**
  While connected to the FreeStyle Auto-Assist Software Version 2.0, the user may synchronize the date and time of the meter with the computer date and time if selected.

Comparison to Predicate Device

Freestyle Auto-Assist Software Version 2.0 has similar data and graphic presentation capabilities to the predicate device, CoPilot™ Health Management System, cleared under K062770.

The similarities between FreeStyle Auto-Assist Software Version 2.0 and the predicate are highlighted below:

Feature	Predicate CoPilot Diabetes Data Management System	Proposed Auto-Assist™ Software Version 2.0
Editing of Patient Data	Does not allow user to edit data retrieved from a meter	Same

Feature	Predicate CoPilot Diabetes Data Management System	Proposed Auto-Assist™ Software Version 2.0
Statistical Functionality Summary	Glucose Statistics: Average blood glucose concentration Number of readings Number of days Target blood glucose range Percent of readings above, below, and within target range Standard deviation of blood glucose readings Insulin Statistics: Avg/Day Avg/Day Total	Same
Hardware Requirements	CD-ROM drive (not required if application is loaded from internet) Mouse Printer (if user wants to print) Internet connectivity (for host or e-mail Communication) Class I fax-enabled modem (required for fax capabilities only) Data Cable USB port	Same
Data Transfer	Serial or Serial/USB adapter Communication cables.	Same
Compatible Blood Glucose Meters	Precision Xtra™ Freestyle Freedom™ FreeStyle Lite FreeStyle Freedom Lite	Same

Feature	Predicate CoPilot Diabetes Data Management System	Proposed Auto-Assist™ Software Version 2.0
Languages	English	Same

The differences between FreeStyle Auto-Assist Software Version 2.0 and the predicate are highlighted below:

Feature	Predicate CoPilot Diabetes Data Management System	Proposed Auto-Assist™ Software Version 2.0
Intended Use	The CoPilot Health Management System is intended for use as an accessory to the Freestyle and Precision Xtra blood glucose monitoring systems and some commercially available blood glucose meters and insulin pumps. The CoPilot Health Management System is intended for use in home and clinical settings to upload data from these devices to a patient's or healthcare professional's computer where the data may be saved, displayed in a number of formats, printed, or exported to an authorized user. The CoPilot System is intended to aid people with diabetes and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results, insulin dosages, and carbohydrate intake data to support an effective diabetes management program.	The FreeStyle Auto-Assist Software Version 2.0 is intended for use by people with diabetes to aid in the review, analysis and evaluation of information such as blood glucose test results, blood ketone test results and other data uploaded from a meter, such as insulin doses and exercise data, in support of an effective diabetes health management program. FreeStyle Auto-Assist software is not intended for the diagnosis of or screening for diabetes mellitus.
Indications for Use	People with diabetes Healthcare Professionals	People with diabetes

Feature	Predicate CoPilot Diabetes Data Management System	Proposed Auto-Assist™ Software Version 2.0
Import Capability	Event Importing: Tab delimited files XML Files Database Importing: Precision Link (V.2.5 or higher) FreeStyle Connect CoZMonitor	No import capability
Compatible Blood Glucose Meters	Precision® Xceed Freestyle® Freestyle Tracker® Freestyle Navigator® Continuous Glucose Monitoring System	Freestyle Insulinx Freestyle 5 K092638 Freestyle Flash K092638
Operating System	Microsoft Windows 98SE 2000 and XP	Microsoft Windows 7 (32 or 64 bit), Vista, or Windows XP Mac OS X Snow Leopard or Lion
Statistical Functionality Summary	Pump Statistics: Avg/Day Meal Bolus Avg/Day Correction Bolus Avg/Day Total Bolus Avg/Day Basal Avg/Day Total Insulin	None
Hardware Requirements	Co-Pilot for FreeStyle Navigator: Pentium 4 or above 512Mb Kensington USB Bluetooth Adapter and compatible Widcomm driver (if downloading data from FreeStyle Navigator)	Not compatible with FreeStyle Navigator
Languages	No Spanish translation	Spanish

Feature	Predicate CoPilot Diabetes Data Management System	Proposed Auto-Assist™ Software Version 2.0
Graphic Data Displays	Glucose data readings are displayed graphically along with the user-defined target range. Glucose data readings above target are displayed as purple and below target range as yellow. Triangle = Discrete data Circle = Continuous data Square = Manually entered glucose Above target = purple Within target = green Below target = yellow	Glucose data readings are displayed graphically along with the user-defined target range Glucose data readings above target are displayed as green, on target as blue, and below target as gray. Open Circle = Average blood glucose Closed Circle = Discrete blood glucose data Up-Arrow = blood glucose value greater than 350mg/dl
Data Transfer	Co-Pilot System for FreeStyle Navigator functionality communicates with FreeStyle Navigator via Kensington Bluetooth adapter/driver.	Micro-USB/USB adapter
Storage Capacity	CoPilot storage capacity is limited by the amount of available hard disk storage space	None

Summary of Testing:
The FreeStyle Auto-Assist Software Version 2.0 underwent verification and validation testing. A brief summary of the tests performed is described below.

These studies demonstrated that the FreeStyle Auto-Assist Software Version 2.0 performed according to the specifications and the intended use.

Software Verification and Validation
FreeStyle Auto-Assist Software Version 2.0 was validated pursuant to the moderate level of concern requirements. Design validation testing confirmed that the software performs according to the stated intended use. Software evaluation consisted of functional testing and code inspections which was performed on FreeStyle Auto-Assist Software Version 2.0's design verification. The software was developed in accordance with FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical*

Devices (May 11, 2005) and *General Principles of Software Validation 1/11/2002: Final Guidance for Industry and FDA Staff*, where applicable and appropriate.

A total of 35 participants of typical computer experience (used computer at least 4 times per week) and ages (age range 18 to 66 years old) that would be expected to use diabetes data management software were enrolled in the Human Factors study conducted for FreeStyle Auto-Assist Software Version 2.0 enrolled . All of the study participants had diabetes: 13 were Type 1 and 22 were Type 2. As part of the study, users installed the software on their test computer desktop and launched the software. Task 1 required the subjects to install the software, Task 2 required subjects to upload meter data and create and print reports, and Task 3 required subjects to save previously generated reports. Users were given either of two meters (16 were tested using Freestyle Freedom Lite meters and 18 with Precision Xtra meters), and were assessed on their ability to upload meter data, create and print reports, and save reports to their desktop. Meters were preloaded with data such as blood glucose or ketone results, based on the compatible meters, and users created reports and graphs using this stored data. Stored data was automatically uploaded from a compatible meter when it was connected to a computer running FreeStyle Auto-Assist Software Version 2.0.

Based on the study, 32 subjects were able to successfully create and view reports, and the data in these reports matched the stored data in 100% of cases.

Statement of Equivalence:
The FreeStyle Auto-Assist Software Version 2.0 is substantially equivalent to the predicate device with regards to its intended use and function. Both the subject and predicate devices are intended to allow people with diabetes to upload data from compatible meters into FreeStyle Auto-Assist Software Version 2.0, where users may review blood glucose and other data in a number of different graphical presentations.

Conclusion:
Based on the information provided in this premarket notification, the FreeStyle Auto-Assist Software Version 2.0 is substantially equivalent to the predicate device and is suitable for its intended use. The software is as safe, as effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 5, 2013

Abbott Diabetes Care Inc.
C/O David G. Lambert
1360 South Loop Road
ALAMEDA CA 94502

Re: K123089
Trade/Device Name: Freestyle Auto-Assist Software Version 2.0
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: February 27, 2013
Received: February 28, 2013

Dear Mr. Lambert:

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,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K123089

Device Name: Freestyle Auto-Assist Software Version 2.0

Indications for Use:

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Freestyle Auto-Assist software is not intended for the diagnosis of or screening for diabetes mellitus

Prescription Use _____ (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 In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k123089