

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

- A. 510(k) Number:
k123089
- B. Purpose for Submission:
New 510(k) for Diabetes Data Manager for use with the Abbott Freestyle Insulinx meter cleared under k111874
- C. Manufacturer and Instrument Name:
Abbott Laboratories
Freestyle auto-assist software version 2.0 with model
- D. Type of Test or Tests performed:
Diabetes data management system
- E. System Descriptions:
1. Device Description:

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.

2. Principles of Operation:
- 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 are retrieved from the meter. The meter settings can be saved to the computer by selecting the backup meter file option.
 - **Report Generation/Printout, Logbook, Glucose Average, Daily Statistics, Meal Event Averages**
 - **Date/Time Synchronization with PC**
3. Modes of Operation:
Does the applicant's device contain the ability to transmit data to a computer webserver, or mobile device? Yes X or No __.
- Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission: Yes __ or No X.
4. Specimen Identification:
Specimen identification is based on time and date of testing.
5. Specimen Sampling and Handling:
Data transmission from compatible meters using capillary whole blood samples
6. Calibration:
Compatible meter specific. See statement below under section J.
7. Quality Control:
Compatible meter specific. See statement below under section J.
8. Software:
FDA has reviewed the applicant's Hazard Analysis and software Documentation: Yes x or No _____

F. Regulatory Information:

| Device Name | Product Code | Classification | Regulation | Panel |
|--|--|----------------|-------------------|-------------------------|
| Glucose Test System | NBW: Blood Glucose Test System, Over-the- Counter | Class II | 21 CFR § 862.1345 | Clinical Chemistry (75) |
| Calculator/Data Processing Module for Clinical Use | JQP: Calculator/ Data Processing Module for Clinical Use | Class I | 21 CFR § 862.2100 | Clinical Chemistry (75) |

G. Intended Use:

1. Indication(s) 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.

2. Special Condition for use Statement(s):

Over the Counter Use

H. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) numbers:

ABBOTT CoPilot™ Health Management System cleared under k062770.

2. Comparison with Predicate Device:**Similarities**

| 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 |
| Intended Use | 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 | Same |

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

Differences

| 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 Freestyle Flash |
| 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 |

I. Standard/Guidance Document Referenced (if applicable):
IEC62366 Medical Devices - application of usability engineering to medical devices

J. Performance Characteristics:
The performance characteristics listed below as applicable, are presented in the specific glucose clearance under k111874

1. Analytical Performance:

The performance characteristics listed below as applicable, were presented in the specific glucose meter clearance under k111874

a. *Accuracy:*

See above statement under section J(1).

b. *Precision/Reproducibility:*

See above statement under section J(1).

c. *Linearity:*

See above statement under section J(1).

d. Carryover:

See above statement under section J(1).

e. Interfering Substances:

See above statement under section J(1).

2. Other Supportive Instrument Performance Data Not Covered Above:

- a. Human Factors Study. A total of 32 of 35 participants were fully evaluated. Subjects were of typical computer experience 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. 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 assessed on their ability to upload meter data, create and print reports, and save reports to their desktop. The Freestyle Freedom Lite meter and the Precision Xtra meter were chosen as meters best representing the line of compatible meter including the Freestyle Insulinx meter and 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, subjects were able to successfully create and view reports, and the data in these reports matched the stored data in 100% of cases.

- b. Ease of Use Evaluation. Ease-of-use ratings for the Auto-Assist 2.0 software were recorded upon task completion in the Human Factors study. Participants were asked to rate the ease of use for each task, on a scale from 1 to 5, where 1 was very easy and 5 was very difficult. At the end of the session, they were also asked to provide an overall rating of the software using the same scale.

The overall success of the majority of participants led to a positive experience with the software. On a 5-point scale where 1 represented very difficult and 5 represented very easy, participants rated all tasks as

relatively easy (Task 1: 4.3, Task 2: 4.1, and Task 3: 4.3). Even when participants struggled with a task or failures occurred, participants still thought that the software would benefit them by helping them better track their diabetes. The participants who struggled assumed they would not have difficulty if they were to use the software again. The benefits of tracking their disease and the assumption that the software was easy to learn gave participants an overall positive impression of the software, which is reflected in the overall ease of use rating of 4.2.

- c. Bench Testing. Bench testing was conducted during design verification activities. The existing FreeStyle and Precision USB Data Cables were used to upload data from compatible meters to the Auto-Assist 2.0 application running on a Windows or Mac Computer. Auto-Assist 2.0 verification was performed on the following supported Operating Systems:
- Windows XP SP3 (32-bit)
 - Windows Vista (32-bit and 64-bit)
 - Windows 7 (32-bit and 64-bit)
 - Mac OS X Snow Leopard
 - Mac OS X Lion

Meter memory capacity and data rollover is a function of meter design and unchanged from those submitted in each meter pre-market application, and thus was not tested as part of FreeStyle Auto-Assist Software Version 2.0. Auto-Assist 2.0 software has been verified to be implemented according to its meter specific data upload requirements to meet 100% accuracy and data management requirements.

- d. Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes.
- e. The Auto-Assist Software Version 2.0 User's Guide Readability Assessment was at a 6.4 grade level using the Flesch-Kincaid readability assessment.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.