

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k073699

B. Purpose for Submission:

New submission for an accessory data management software application for glucose meters

C. Measurand:

Whole Blood Glucose

D. Type of Test:

The MyCare Team (MCT)-Diabetes is a software-only medical device which serves as an internet-based accessory which interfaces between the software in personal glucose monitoring devices and the MCT general-purpose health management database.

E. Applicant:

MyCare Team, Inc.

F. Proprietary and Established Names:

MCT-Diabetes

G. Regulatory Information:

1. Regulation section:

21CFR Sec.- 862.1345-Glucose test system.

21CFR Sec.-862.2100 - Calculator/data processing module for clinical use.

2. Classification:

Class II and I, respectively

3. Product code:

NBW - System, Test, Blood Glucose, Over the Counter

JQP-Calculator/Data Processing Module, For Clinical Use

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications(s) for use below

2. Indication(s) for use:

The MCT-Diabetes™ software serves as an interface between the software in personal glucose monitoring devices and a general purpose health management database to assist in the review, analysis and evaluation of blood glucose test

results. MCT Diabetes is designed for home use and professional healthcare settings.

3. Special conditions for use statement(s):

Not Applicable

4. Special instrument requirements:

Compatible glucose meters for home use such as glucose meters by Roche Diagnostics, Bayer, BD, Johnson & Johnson, Abbott, and Nova Biomedical.

I. Device Description:

MCT-Diabetes is a software-only device. MCT-Diabetes allows the patient to transfer their blood glucose readings from their glucose meter(s) over a secure connection to the MCT-Diabetes server. The glucose readings are then stored in a secure database for the patient to review. MCT-Diabetes allows the patient to group their readings into specific timeslots and then review their readings for each timeslot over long periods of time. This type of analysis provides the patient with a better view of how they are managing their diabetes and the convenience of viewing the output from all blood glucose monitors in one place. The patient can then also allow others that assist them in the management of their disease to view their data and send secure messages back to the patient about their readings.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Home Diagnostics, Inc., TrackRecord Data Management Software

2. Predicate 510(k) number(s):

k070593

3. Comparison with predicate:

	MCT-Diabetes (New Device)	Predicate Device TrackRecord Data Management Software (k070593)	EQUIVALENT OR DIFFERENT
COMPARISON OF GENERAL CHARACTERISTICS			
Indications for Use Statement	The MCT-Diabetes™ software serves as an interface between the software in personal glucose monitoring devices and a general purpose health management database to assist in the review, analysis and evaluation of blood glucose test results. MCT Diabetes is designed for home use and professional healthcare settings.	TrackRecord Data Management Software is intended for use in the home or in clinical settings, for single or multi-patient use, to assist people with diabetes as well as their healthcare professionals in the review, analysis and evaluation of historical blood glucose test results to support effective diabetes management.	Equivalent
Intended Use	Home use or Clinical Assist diabetics, families, and professionals in management of blood glucose Support diabetes management Single or multi-patient use	Home use or Clinical Assist diabetics, families, and professionals in management of blood glucose Support diabetes management Single or multi-patient use	Equivalent
Data Source	Compile data from multiple different brands of glucose meters for display in one place on user's personal computer	Compile data from Home Diagnostics brand glucose meters	Equivalent
Classification	NBW, system, test, blood glucose, over the counter 862.1345, Class II JQP, calculator/data processing module, for clinical use, 862.2100, Class I	NBW, system, test, blood glucose, over the counter 862.1345, Class II JQP, calculator/data processing module, for clinical use, 862.2100, Class I	Equivalent
Panel	Clinical Chemistry	Clinical Chemistry	Equivalent
Software Use	Single (individual) or multiple user (clinical) settings	Single or multiple user settings	Equivalent
Use in Clinic	Patient list available	Search for specific patient	Equivalent
Report types	Logbook Readings Line Chart Average Bar Chart Percentage Pie Chart	Logbook Glucose Trend Pie Chart (Conformance) Summary	Equivalent

	MCT-Diabetes (New Device)	Predicate Device TrackRecord Data Management Software (k070593)	EQUIVALENT OR DIFFERENT
	Percentage Readings by Time of Day		
COMPARISON OF TECHNICAL SPECIFICATIONS			
Special Glucose Monitor Instrument Requirements	<p>Wide range of supported meters are listed on website;</p> <p>As additional software protocols are obtained and devices are validated, capabilities will be broadened to include other blood glucose meters</p>	Home Diagnostics brand blood glucose meters only	<p>Different</p> <p>However, the same validation/verification of software protocols (from blood glucose manufacturers) with MyCare Team software prior to addition to list</p>
Capable of uploading data from various glucose monitoring devices? Software download requirements	<p>Yes. Acceptable devices are listed and include the majority of currently available devices. Software resides on the Internet and not on the User's Personal Computer (PC)</p>	<p>Yes, for Home Diagnostics brand monitors.</p> <p>Software driver must be uploaded on the device or installed on the PC</p>	Equivalent
User's Personal Computer (PC) Requirements	<p>Windows 98 Second Edition (SE), Windows 2000 and Windows XP Home and Professional</p> <p>600 MHz Intel Pentium III or equivalent</p> <p>Minimum 128 MB RAM</p> <p>100-200 MB RAM used</p>	<p>Windows 98 Second Edition (SE), Windows 2000 and Windows XP Home and Professional</p> <p>600 MHz Intel Pentium III or equivalent</p> <p>Minimum 128 MB RAM</p> <p>100-200 MB RAM used</p>	<p>Equivalent</p> <p>Equivalent</p> <p>Equivalent</p> <p>Equivalent</p>
User's Personal Computer (PC) Requirements			

	MCT-Diabetes (New Device)	Predicate Device TrackRecord Data Management Software (k070593)	EQUIVALENT OR DIFFERENT
	during installation and 100 MB used after installation	during installation and 100 MB used after installation	
	CD ROM drive	CD ROM drive	Equivalent
	Manufacturer's required cable can be ordered as a service to the customer.	9-pin/25-pin COM or USB port required with a serial or USB data cable CD ROM required	Equivalent
	Installed from MyCareTeam Website	Installed using CD	Different Installation is performed via the Internet; thus, no CD is required
Technical Support	Yes	Yes	Equivalent
User's Manual	Available on Internet while using program ("Help System")	Link via icon	Equivalent Both programs have Help system (but different access)
Cable Availability	Manufacturer cable ordered for customer at their request; original manufacturer equipment with no re-labeling	Serial cable, cable available separately	Equivalent
Auto-detect COM port	Yes	Yes	Equivalent
Installation of program	Installed from internet link	Installed using CD	Equivalent
DATA INPUT AND OUTPUT			
Required data on patient entry includes patient ID, name, address, etc.	Yes	Yes	Equivalent
Insurance information	No	Yes	Different
Physician information	Multiple individuals	Multiple individuals	Equivalent
Diabetes educator information	Multiple individuals	Multiple individuals	Equivalent
Types of information that can be manually	Insulin list, medication list, exercise, blood pressure	Insulin list and medication list	Different More information

	MCT-Diabetes (New Device)	Predicate Device TrackRecord Data Management Software (k070593)	EQUIVALENT OR DIFFERENT
entered	data, laboratory results		can be entered in MCT-Diabetes

K. Standard/Guidance Document Referenced (if applicable):

Software guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Issued May 11, 2005.
- General Principles of Software Validation. Issued January 11, 2002.
- Guidance for Off-the-Shelf Software Use in Medical Devices. Issued September 9, 1999.
- Guidance for Industry – Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software. Issued January 14, 2005.

Non-Software guidance and standards

- ISO 15197: 2003. In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. First edition.
- Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems. Issued 10/24/2006.
- ISO 14971: 2007. Medical Devices – Application of risk management to medical devices. Second edition.

L. Test Principle:

The MyCare Team (MCT)-Diabetes software is an accessory to compatible meters, which use specific test principles such as in Accu-Chek Active (k021827), Accu-Chek Advantage (k000365), Accu-Chek Aviva (k043474), Accu-Chek Compact (k022171), Accu-Chek Compact Plus (k031755), Accu-Chek Complete (k000364), Ascensia Breeze (k024062), Ascensia Breeze 2 (k062347), Ascensia Contour (k023657), Ascensia Dex 2 (k963500), Ascensia Elite XL (k951537), BD Logic (k022581), BD Paradigm Link (k040603), Lifescan OneTouch Profile (k950727), Lifescan OneTouch Ultra (k011479), Lifescan OneTouch Ultra 2 (k053529), Lifescan OneTouch Ultra Smart (k021819), MediSense Optium (k051213), MediSense Precision Xtra (k040814), Nova Max (k040603), TheraSense FreeStyle (k012014), TheraSense FreeStyle Freedom (k051839), TheraSense FreeStyle Lite (k070850).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
see above associated devices
 - b. *Linearity/assay reportable range:*
see above associated devices
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
see above associated devices
 - d. *Detection limit:*

- see above associated devices
 - e. *Analytical specificity:*
 - see above associated devices
 - f. *Assay cut-off:*
 - see above associated devices
2. Comparison studies:
- a. *Method comparison with predicate device:*
 - see above associated devices
 - b. *Matrix comparison:*
 - Not Applicable
3. Clinical studies:
- a. *Clinical Sensitivity:*
 - Not Applicable
 - b. *Clinical specificity:*
 - Not Applicable
 - c. Other clinical supportive data (when a. and b. are not applicable):

Usability studies were designed to test human factors such as ease of operation, readability of the measured results, unambiguous messages to the user, and evaluation of the instructions for use (i.e., the help features) as described in Sections 4.4 and 8.4 of ISO 15197:2003 and in Section 3 of the FDA Total Product Life Cycle guidance document (2006). As recommended in Section 8.3 of ISO 15197, study participants were given two surveys to evaluate their understanding of the system and were not given additional training, instructions, or assistance than those routinely provided with the MCT-Diabetes system. The studies were conducted in September and October 2006, respectively, with 47 completed responders out of 65 total participants.

The survey group included a near-even representation of individuals with Type 1 and Type II diabetes, including both children and adults. All responses were kept confidential and participants remained anonymous throughout both surveys. Data were reported in aggregate and no identifying information was linked back to individual responses.

The human factors that were most applicable to this software-only device are the user characteristics (individuals with vision problems must be able to understand the system) and the device-user interface ensuring ease of operation, readability of the result, and unambiguous messages to the user.

The first survey was designed to evaluate the set up process for MCT-Diabetes, including registering with MyCare Team, uploading of blood glucose data, and the initial display of the blood glucose data. The outcome of this survey resulted in the following changes to the MCT-Diabetes software:

- Enhancements to the Active X control for uploading data from various meters in order to make the upload process proceed more smoothly from USB ports.
- Support for additional meters
- Additional error-checking and updated help files for users

The second survey was designed to evaluate the usability experience for the participants including evaluations of all features of the MCT-Diabetes software. The outcome of this survey resulted in the following changes to the MCT-Diabetes software:

- Redesign of the user interface for a number of web pages, including new icons for better readability and navigation.
- Addition of new features & functionality, including date of last upload, user setting of blood glucose ranges, and user adjustment of times of day

The usability testing and results was factored appropriately into the Risk Analysis. As problems were identified, software changes were made and documented. The final version after usability testing was identified as Version 2.0.

4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:
see above associated devices

N. Instrument Name:

MyCare Team, Inc, MCT-Diabetes software

O. System Descriptions:

1. Modes of Operation:

MCT-Diabetes provides a Web Based user interface that is compatible with Microsoft Internet Explorer and Mozilla FireFox. The data upload control is not directly accessible by the user, but only as provided through the web based user interface.

- Windows 98 Second Edition (SE), Windows 2000 and Windows XP Home and Professional
- 600 MHz Intel Pentium III or equivalent
- Minimum 128 MB RAM
- 100-200 MB RAM used

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

3. Specimen Identification:

Meter controlled, by time and date stamp

4. Specimen Sampling and Handling:

Not Applicable

5. Calibration:

Not Applicable

6. Quality Control:

Not Applicable

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Q. Proposed Labeling:

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

R. Conclusion:

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