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:
<table>
<thead>
<tr>
<th><strong>MCT-Diabetes (New Device)</strong></th>
<th><strong>Predicate Device TrackRecord Data Management Software (k070593)</strong></th>
<th><strong>EQUIVALENT OR DIFFERENT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMPARISON OF GENERAL CHARACTERISTICS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Indications for Use Statement</strong></td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>Home use or Clinical Assist diabetics, families, and professionals in management of blood glucose Support diabetes management Single or multi-patient use</td>
<td>Home use or Clinical Assist diabetics, families, and professionals in management of blood glucose Support diabetes management Single or multi-patient use</td>
</tr>
<tr>
<td><strong>Data Source</strong></td>
<td>Compile data from multiple different brands of glucose meters for display in one place on user's personal computer</td>
<td>Compile data from Home Diagnostics brand glucose meters</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td>NBW, system, test, blood glucose, over the counter 862.1345, Class II JQP, calculator/data processing module, for clinical use, 862.2100, Class I</td>
<td>NBW, system, test, blood glucose, over the counter 862.1345, Class II JQP, calculator/data processing module, for clinical use, 862.2100, Class I</td>
</tr>
<tr>
<td><strong>Panel</strong></td>
<td>Clinical Chemistry</td>
<td>Clinical Chemistry</td>
</tr>
<tr>
<td><strong>Software Use</strong></td>
<td>Single (individual) or multiple user (clinical) settings</td>
<td>Single or multiple user settings</td>
</tr>
<tr>
<td><strong>Use in Clinic</strong></td>
<td>Patient list available</td>
<td>Search for specific patient</td>
</tr>
<tr>
<td><strong>Report types</strong></td>
<td>Logbook Readings Line Chart Average Bar Chart Percentage Pie Chart</td>
<td>Logbook Glucose Trend Pie Chart (Conformance) Summary</td>
</tr>
<tr>
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</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Percentage Readings by Time of Day</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**COMPARISON OF TECHNICAL SPECIFICATIONS**

| Special Glucose Monitor Instrument Requirements | Wide range of supported meters are listed on website; As additional software protocols are obtained and devices are validated, capabilities will be broadened to include other blood glucose meters | Home Diagnostics brand blood glucose meters only | Different
<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Capable of uploading data from various glucose monitoring devices? Software download requirements</td>
<td>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)</td>
<td>Yes, for Home Diagnostics brand monitors. Software driver must be uploaded on the device or installed on the PC</td>
<td>Equivalent</td>
</tr>
</tbody>
</table>

User's Personal Computer (PC) Requirements

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

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

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

Non-Software guidance and standards

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 Dexp 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.

• 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.