K073699

MAR 2 6 2008

510(k) Summary
MCT-Diabetes™

Name of Device:	MCT Diabetes™, Version 2.0
Product Code, Class No. 1:	NBW, Class II
Classification No. 1:	862.1345 (System, Test, Blood Glucose, Over the Counter)
Product Code, Class No. 2:	JQP, Class I
Classification No. 2:	862.2100 (Calculator/data processing module, for clinical use)
Review Panel:	Clinical Chemistry Devices

Sponsor:	MyCareTeam, Inc. 40 Nagog Park Acton, MA 01720
Contact:	John Paglierani
Telephone:	(978) 635-6960, Ext. 5122
Fax:	(508) 347-0242

Date Prepared:	December 31, 2007

A. LEGALLY MARKETED PREDICATE DEVICE

Name of Predicate:	K070593, TrackRecord Data Management Software, Home Diagnostics Inc.
Product Code, Class No. 1:	NBW, Class II
Classification No. 1:	862.1345 (System, Test, Blood Glucose, Over the Counter)
Product Code, Class No. 2:	JQP, Class I
Classification No. 2:	862.2100 (Calculator/data processing module, for clinical use)

B. DEVICE DESCRIPTION

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. It is an accessory device to most manufactured models home-use blood glucose monitors, including glucose monitoring devices by Roche Diagnostics, Bayer, BD, Johnson & Johnson, Abbott, and Nova Biomedical. The list of supported devices is located at *www.mycareteam.com.*

The purpose of the electronic diabetes management system is to help the user manage their own blood sugar information to better regulate diabetes treatments and control blood glucose. The **MCT-Diabetes** system holds a convenience function, as the user

can upload blood glucose data from a variety of currently marketed blood glucose monitors into one location for viewing.

Finally, after the user transmits and stores blood glucose data to the secure database, the **MCT-Diabetes** system allows family members and/or healthcare professionals who have permission from the primary user and a password to view and monitor the user's data and reports. Four different types of chart displays are available, and the user selects the time period and the type of output. The subject can view their blood glucose information over time and can compare to previous time periods, to help the subject better manage their disease over time. The subject can also enter and track other health-related information such as body weight, blood pressure, and level of exercise.

C. INTENDED 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.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **MCT-Diabetes** is not substantially different from the predicate device, the TrackRecord Data Management Software. Both this and the predicate device, which has the same classification numbers as the **MCT-Diabetes**, is intended to serve as an interface between personal glucose monitoring devices and a health management database to assist in the monitoring of an individual's blood glucose levels. Both devices are designed for both home use and use by healthcare professionals.

The **MCT-Diabetes** has the same technological characteristics as the predicate device with small exceptions (e.g., the predicate device program is distributed on a CD while this device is Internet-based only), but those exceptions do not affect safety or effectiveness. Any differences in technology have been addressed by software validation and verification testing, and usability testing (conducted in accordance with ISO 15197: 2003). The decision algorithm brings us to a determination of Substantial Equivalence, as defined in the Federal Food, Drug, and Cosmetic Act.

E. TECHNOLOGICAL CHARACTERISTICS

The **MCT-Diabetes** device is an Internet-based software device that has physical requirements common to most home personal computers users (Pentium 4 microprocessor or greater, 256Mb of RAM memory, 10Gb secondary storage,

Microsoft Internet Explorer v6.0 or later, etc.). The **MCT-Diabetes** device is a secure device and meets or exceeds HIPAA Guidelines for data and patient security.

F. TESTING

Software verification and validation testing were conducted in compliance with FDA Quality System Guidelines. MCT-Diabetes was considered a Moderate level of concern.

The MCT-Diabetes device was tested for usability by the American Diabetes Association (ADA). Two surveys were sent to the users independent of MyCareTeam Inc and only tabulated by the American Diabetes Association to test the usability of the system. Results from the first survey respondents were used for system improvements, although the vast majority of responses were positive. Results from the second survey revealed positive outcomes regarding the user interaction with the device and its operation. The overall results from user testing demonstrate that the **MCT-Diabetes** performs according to its intended use and reliably transmits blood glucose data in a way that is understandable to the user and fits the Intended Use of the device.

G. CONCLUSIONS

MyCareTeam, Inc. has demonstrated through its comparison of characteristics of **MCT-Diabetes** with the predicate device, and through software controls and Usability Testing, that **MCT-Diabetes** is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 6 2008

MyCare Team, Inc.
c/o Diane Mandell Horwitz, Ph.D.
Mandell Horwitz Consultants LLC
P.O. Box 2552
Fairfax, VA 22031

Re: k073699
Trade/Device Name: MCT-Diabetes™
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: December 31, 2007
Received: December 31, 2007

Dear Dr. Horwitz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K073699

Device Name: MCT-Diabetes™

Indication 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.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _X_ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073699