

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

A. 510(k) Number:

k070593

B. Purpose for Submission:

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

C. Measurand:

Glucose

D. Type of Test:

An accessory device, the TrackRecord DMS, for diabetes management, is a stand-alone optional data management software accessory supplied in CD format for use with Home Diagnostics brand Smart System blood glucose meters such as the TrueTrack and Prestige IQ Smart System meters. The software is installed onto a personal computer (PC) and the blood glucose meter is connected to the PC via a data cable (k040670). When used with TrueTrack or Prestige IQ meters, TrackRecord DMS permits the management of blood glucose data transferred from the meter memory to the computer for enhanced data management capability.

E. Applicant:

Home Diagnostics, Inc.

F. Proprietary and Established Names:

TrackRecord Data Management Software

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 indication(s) for use.

2. Indication(s) for use:

TrackRecord Data Management Software (DMS) 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.

3. Special conditions for use statement(s):

Not Applicable

4. Special instrument requirements:

Home Diagnostics brand Smart System blood glucose meters such as the TrueTrack and Prestige IQ Smart System meters.

TrackRecord DMS is compatible with Windows 98 Second Edition (SE), Windows 2000 and Windows XP Home and Professional. The software operates per 600 MHz Intel® Pentium® III or equivalent, with a minimum 128 MB of RAM, and uses 100 - 200 MB during installation and 100 MB after installation. A 9-pin / 25-pin COM or USB port is required with a serial or USB data cable. A CD-ROM is required.

I. Device Description:

Software application features include data management for single at-home patient use and multiple-patient use for the healthcare professional in the clinical setting. Users can input patient healthcare and ID information, and select date range, glucose units, target glucose ranges, and meal time blocks.

Five reports are available:

- 1) Summary Report that combines the reports listed below.
- 2) Electronic Log Book that displays glucose results in a similar manner to a paper log book
- 3) Conformance Report to graphically represent the percentages of glucose results outside the target range and below the hypoglycemic threshold previously set up by the user.
- 4) Trend Report to show a graphical representation of daily blood glucose results.
- 5) Extended Log Book Report is a more comprehensive report than the Log Book Report displaying patient information, glucose target and hypoglycemic ranges, reference method, date of the report, and date range of 2 glucose results. The report calculates the average result for the time slot, the number of results above the target range for that time slot, the number of results below the target range for that time slot, the number of hypoglycemic results for that time slot, and the percentages for above target, below target, within target, and hypoglycemic.

J. Substantial Equivalence Information:

1. Predicate device name(s):
LifeScan IN TOUCH Diabetes Management System
2. Predicate 510(k) number(s):
k984527
3. Comparison with predicate:

Similarities		
	IN TOUCH Diabetes Management Software	TrackRecord Data Management System
Installation of program	Installed using CD	Installed using CD

Similarities		
	IN TOUCH Diabetes Management Software	TrackRecord Data Management System
Package Contents	Choice of Software and Electronic Instructions for Use/Registration – or– Software, Electronic Instructions for Use/Registration and USB/9 pin	Choice of Software and Electronic Instructions for Use/Registration – or– Software, Electronic Instructions for Use/Registration and USB/9 pin
Cable availability	Serial Cable, Cable available separately	Serial Cable, Cable available separately
Capable of uploading data from various devices	Software driver must be uploaded on the device or installed on PC.	Software driver must be uploaded on the device or installed on PC.
Computer System Requirements	9-pin or 25 pin COM or USB port	9-pin or 25 pin COM or USB port
	CD-ROM drive	CD-ROM drive
	Windows Operating System 98 SE	Windows Operating System 98 SE
	Windows 2000 Professional, and	Windows 2000 Professional, and
	Windows XP Home and Professional.	Windows XP Home and Professional.
	Minimum of 128 MB of RAM.	Minimum of 128 MB of RAM.
	100-200 MB minimum free hard disc space during installation, 100 MB after installation.	100-200 MB minimum free hard disc space during installation, 100 MB after installation.
	Video Monitor and adapter with at least 800x600 pixel screen resolution and 256 colors	Video Monitor and adapter with at least 800x600 pixel screen resolution and 256 colors
Software use indications	Home or clinic settings	Single or Multiple user settings.
Manual Entry	Ability to add records manually.	Ability to add records manually.
Copy database to separate file.	Yes	Yes
Deleting Results	Only Manual entry results may be deleted.	Only Manual entry results may be deleted.
Deleting Patients and all accompanying records.	Yes	Yes

Similarities		
	IN TOUCH Diabetes Management Software	TrackRecord Data Management System
Copy saved database back to active DMS database.	Yes	Yes
Ability to default to manufacturer settings (mealtime slots, target glucose ranges, etc.)	Yes	Yes
Language capabilities	English, Spanish	English, Spanish
Ability to uninstall DMS program	Yes	Yes
Ability to access DMS program via icon or explorer.	Yes	Yes
Viewing the Owner's Manual	Link provided via icon.	Accessed via Help on toolbar or F1 on computer
Search for specific patient in multiple (clinic) user function.	Yes	Yes
Default glucose target ranges available	Yes	Yes
Ability to personalize target ranges.	Yes	Yes
Customizable schedule	Yes	Yes
Search patient capability	Yes	Yes
Result type display	Choice of whole blood or plasma result types.	Choice of whole blood or plasma result types.
Units of measure display	Choice of mmol/L or mg/dL	Choice of mmol/L or mg/dL
Ability to enter hypoglycemic range	Yes	Yes
Ability to set default favorite report.	Yes	Yes
Report Types	Logbook, Glucose Trend, Pie Chart (Conformance), Summary	Logbook, Glucose Trend, Pie Chart (Conformance), Summary
Ability to synchronize meter clock to PC upon download	Yes	Yes
Ability to display 12 or 24 hour clock format	Yes	Yes
Ability to change date format	Yes (mm/dd/yy or dd/mm/yy)	Yes (mm-dd-yy, mmm-dd-yyyy or yyyy-mm-dd)

Similarities		
	IN TOUCH Diabetes Management Software	TrackRecord Data Management System
Auto-detect COM port	Yes	Yes
Downloaded results cannot be edited or deleted	Yes	Yes
Technical support	Yes	Yes

Differences		
	IN TOUCH Diabetes Management Software	TrackRecord Data Management System
Units of measure automatically set by country in setup installation.	Yes	No
Ability to link to older database versions.	Yes	No older versions available at this time.
Required information on patient entry.	No	Yes, Patient ID (multiple users only), patient name (first and last), street address, and city.
Insurance information	Only one insurance provider may be entered.	Two insurance providers may be entered.
Doctor information	One doctor may be entered.	Two doctors may be entered.
Diabetes Educator information	One diabetes educator may be entered.	Two diabetes educators may be entered.
Diabetes control	Insulin list, medication list, diet/exercise options	Limited to insulin list and medication list
Ability to limit result selection by last transfer	Yes, with the exception of the IN TOUCH Ultra	No
Indication for primary test method.	Not available.	Fingerstick or alternate site.
Specifying/Entering medications/insulin	Yes, up to 3 different medications/insulin types	Unlimited
Ability to enter insulin regiment	Yes	No
Ability to specify complications associated with diabetes by patient	Yes	No
Ability to set default target range by diabetes type (Type I, Type II Gestational, etc.),	Yes	No

Differences		
	IN TOUCH Diabetes	TrackRecord Data Management
	Management Software	System
Report types	Standard Day, Average Readings, Insulin, Exception, Data List, Histogram, Health Checks	Others available, not these specific types
Ability to view results and sort without generating report	No	On screen results may be sorted by individual meter (serial number), date, time, result, time-slot, control results, and manual entry result
Ability to view control results	No	Yes
Ability to set meter clock to a specific date and time	Yes	No
Ability to show cholesterol results/select units of measure	Yes	No
Ability to modify meter average results	Yes, 7, 14, 30,60, or 90 days	No
Change meter audio cues	Yes	No
Ability to clear meter results in memory	Yes	No
Ability to input additional information on patient and downloaded results	Yes – Insulin doses, carb data, exercise data, health notes, comments	No
Ability to email report from PC directly from program	Yes	No
Ability to enter test site for manual result entry	Yes	No
Ability to input additional information on patient	Yes - medication dosing, exercise data, food data, health records, health notes/data,	No
Ability to input additional information on manual result	Yes – test site, comments,	No

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

CLSI (NCCLS) GP14-A, Labeling of Home-Use In Vitro Testing Products.

FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

L. Test Principle:

The TrackRecord DMS is an accessory to the TrueTrack and Prestige IQ Smart System meters, see k030703 and k010403 respectively for meter test principle.

M. Performance Characteristics (if/when applicable):

The TrackRecord DMS is an accessory device to Home Diagnostics brand Smart System blood glucose meters such as the TrueTrack (k030703) and Prestige IQ Smart System (k010403) meters

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:*
see above associated devices
3. Clinical studies:
 - a. *Clinical Sensitivity:*
see above associated devices
 - b. *Clinical specificity:*
see above associated devices
 - c. Other clinical supportive data (when a. and b. are not applicable):
A Human Factors Study using 101 subjects was conducted to evaluate the TrackRecord DMS with the following objectives:
 1. To evaluate design and ease-of-use
 2. To document participant feedback on the features / functions
 3. To document Observer feedback on participant performance
 4. To validate the user instructions are accurate and easy to follow
 5. To evaluate participant ratings with respect to features / functions
 6. To report any discrepancies (bugs/error messages) found during the evaluation

These objectives address ease-of-use, instructions for use and product labeling information. This study was comprehensive and included application tests (feature/function tests) and questionnaire items. The subjects (Users) had

never used TrackRecord DMS and had no prior exposure to TrackRecord DMS or its corresponding Instructions for Use.

Subjects were required to have a minimum of basic computer skills and feel comfortable using a Windows-based Operating System. The study subjects consisted of a mixture of healthcare professionals (multiple patient usage) and persons representing home users (single patient usage).

Conclusions were based on the subjects' ability to demonstrate by usage and evaluation (rating) of features/functions (recorded as responses to 21 feature/function tests), their understanding of the applications of the DMS software, their understanding of how to use the software (install, upload/enter data and patient information, and generate/print reports), their comprehension of the contents of the instructions for use, as well as user assessment of ease-of-use based on a separate questionnaire. The 21 feature/function tests per user were divided into 5 main categories:

- 1) Installation
- 2) User Interface / Owner's Manual
- 3) Set up
- 4) Downloading Results
- 5) Patient Management / Reports

Performance of each User was recorded and evaluated by HDI study administrators (Observers), who are familiar with proper use of TrackRecord DMS. Observers rated each subject's performance using four general questions as follows:

- 1) Subject was successful in installing the DMS program?
- 2) Report printouts were accurate and complete?
- 3) Subject performed required functions satisfactorily?
- 4) Subject accessed "Help" and Technical Support contact information?

Data forms completed by both Users (study subjects) and Observers were provided. Evaluation of the data was performed by an Expert Review Panel, comprised of professionals with expertise in the areas of medical device design, customer and technical support, product quality and quality assurance, and clinical application of the product class.

4. Clinical cut-off:
see above associated devices
5. Expected values/Reference range:
see above associated devices

N. Instrument Name:

Home Diagnostics TrackRecord DMS - accessory to Home Diagnostics brand Smart System blood glucose meters such as the TrueTrack (k030703) and Prestige IQ Smart System (k010403) meters.

O. System Descriptions:

1. Modes of Operation:

Windows Operating System 98 SE Windows 2000 Professional, and Windows XP Home and Professional. Minimum of 128 MB of RAM. 100-200 MB minimum free hard disc space during installation, 100 MB after installation. Video Monitor and adapter with at least 800x600 pixel screen resolution and 256 colors. The application is a Microsoft Access developed database.

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:

The TrackRecord DMS has single or multiple patient capabilities. The application determines which patient owns the glucose meter so the results can be properly assigned to that patient. The meter serial number is the link to the patient record. A patient can have more than one meter serial number, but one meter serial number cannot belong to more than one patient.

The TrueTrack meter can upload from zero to 365 glucose results, plus up to one glucose control result.

The Prestige IQ meter can upload from zero to 365 glucose results, plus up to 12 glucose control results and up to 6 Standard Strip results.

4. Specimen Sampling and Handling:

Capillary whole blood

5. Calibration:

See k030703 and k010403

6. Quality Control:

See k030703 and k010403

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

Not Applicable

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.