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

A. 510(k) Number:
   k081726
B. Purpose for Submission:
   New submission for an accessory data management software application for
   glucose meters
C. Manufacturer and Instrument Name:
   Tyson Bioresearch, Tysonbio Link Health Management System
D. Type of Test or Tests performed:
   Tysonbio Link Health Management System 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 Tysonbio Link Health Management
   System.
E. System Descriptions:
   1. Device Description:
      The TysonBio Link Health Management System software provides users the
      ability to export data from compatible TysonBio meters to a computer via a
      cable connecting to the computer's required USB port. The TysonBio Link
      HMS is a Microsoft Windows based software application for diabetes data
      management. TysonBio Link HMS software is designed to operate an Intel
      compatible PC with Microsoft Windows 2000/XP or later operating system.
      The export of the data allows the data to be viewed only in the TysonBio Link
      HMS software. Aside from the ability to export the data stored in the meter's
      memory, the software also allows the ability to clear the meter's memory.
      Data transferred from the device cannot be changed or modified.
   2. Principles of Operation:
      The TysonBio Link Health Management System is an accessory to compatible
      meters: EZ Smart-608 series meter (k062829), DIACHEX series Blood
      Glucose Meter (k072854), and DIACHEX+ series Blood Glucose Meter
      (k073492)
   3. Modes of Operation:
      TysonBio Link HMS is compatible with Microsoft® Windows® 2000/XP
      version 2
      Hardware specifications:
         Intel® Pentium® III 850 MHz processor or better
         Minimum 128MB of RAM or better
         Minimum 100 MB of free hard disk space or more
         USB port
         TysonBio Link PC link Cable
         Mouse and keyboard
         Printer for printing reports
   4. Specimen Identification:

Meter controlled

5. <u>Specimen Sampling and Handling:</u>
   Not Applicable
6. <u>Calibration:</u>
   Not Applicable
7. <u>Quality Control:</u>
   Not Applicable
8. <u>Software:</u>

   FDA has reviewed the applicant's Hazard Analysis and software
   Documentation: Yes___X__ or No _____

F.   Regulatory Information:

1. <u>Regulation Section:</u>
   21CFR §862.1345 -Glucose test system.
   21CFR Sec.-862.2100 - Calculator/data processing module for clinical use.
2. <u>Classification:</u>
   Class 2 and 1 respectively
3. <u>Product Code:</u>
   NBW - System, Test, Blood Glucose, Over The Counter
   JQP-Calculator/Data Processing Module, For Clinical Use
4. <u>Panel:</u>
   Chemistry (75)

G.   Intended Use:

1. <u>Indication(s) for Use:</u>
   The TysonBio Link Health Management System is an optional software
   accessory for use with the following models with data management
   capabilities: a) EZ Smart-608 series meter, b) DIACHEX series Blood
   Glucose Meter, and c) DIACHEX+ series Blood Glucose Meter. When used
   with one of these meters, TysonBio Link Health Management System
   transfers data from the device's memory into a computer for enhanced data
   management.

   TysonBio Link Health Management System is intended for use in home and
   clinical settings to aid people with diabetes and their health care professionals
   in the review, analysis and evaluation blood glucose test results to support
   effective diabetes management. It should be noted that the software does not
   recommend any medical treatment or medication dosage level.
2. <u>Special Condition for use Statement(s):</u>
   Not Applicable

H.   Substantial Equivalence Information:

1. <u>Predicate device name(s)and 510(k) numbers:</u>
   Lifescan, In Touch Diabetes Management Software (k984527)

2. Comparison with Predicate Device:
Similarities

Items	IN TOUCH DIABETES Management Software	TysonBio Link Health Management System
Intended Use	The IN TOUTCH Diabetes Management Software is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in the review, analysis and evaluation blood glucose test results to support effective diabetes management.	TysonBio Link Health Management System is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in the review, analysis and evaluation blood glucose test results to support effective diabetes management. It should be noted that the software does not recommend any medical treatment or medication dosage level
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 install PC	Same
Computer system requirements	Minimum of 128 MB of RAM	Minimum of 128 MB of RAM or better
	100-200 MB minimum free hard disk space during, 100 MB after installation	Minimum 100 MB of free hard disk space or more
	9-pin or 25 pin COM or USB port	USB port
	Video monitor and adapter with at least 800x600 pixels screen resolution and 256 colors	Same
Software use indications	Home or clinic settings	Single or multiple user settings
Deleting patients and all accompanying records	Yes	Yes

Items	IN TOUCH DIABETES Management Software	TysonBio Link Health Management System
Ability to uninstall program	Yes	Yes
Ability to personalize target ranges	Yes	Yes
Unit of measure display	Choice of mmol/L or mg/dL	mmol/L or mg/dL
Ability to enter hypoglycemic range	Yes	Yes
Report Types	Data list, data statistics, average reading, pie chart, Line graph, histogram,	Data list, data statistics, average reading, pie chart, Line graph, histogram,
Auto-detect COM port	Yes	Yes
Downloaded results cannot be edited or deleted	Yes	Yes
Ability to modify meter average results	Yes,7,14,30,60,90 days	Yes
Ability to clear meter results in memory	Yes	Yes
Required information on use entry	Yes	Yes, user ID, name, photo

Differences

Items	IN TOUCH DIABETES Management Software	TysonBio Link Health Management System
Computer system requirements	Windows operating system 98 SE, Windows 2000, Windows XP home and Professional	only Windows 2000, Windows XP home and Professional
Manual Entry	Ability to add records manually	No
Copy database to separate file	Yes	No
Deleting results	Yes	No

Items	IN TOUCH DIABETES Management Software	TysonBio Link Health Management System
Language capabilities	English, Spanish	English
Viewing the Owner's manual	Link provided via icom	No
Default glucose target ranges available	Yes	No
Search patient capability	Yes	No
Result type display	Choice of whole blood or plasma result types	No
Ability to set default favorite report	Yes	No
Ability to synchronize meter clock to PC upon download	Yes	No
Ability to display 12 or 24 hour clock format	Yes	No
Ability to change date format	Yes	No
Ability to link to older database versions	Yes	No old versions available at this time
Diabetes Educator information	One diabetes educator may be entered	No
Diabetes control	Insulin list, medication list, diet/exercise options	No
Specifying/Entering medication/insulin	Yes, up to 3 different medications/insulin types	No
Ability to enter insulin regiment	Yes	No
Report types	Standard Day, Average Reading, Insulin, Exception, Data List Histogram, Health checks	No Insulin, Exception, standard day report.
Ability to set meter	Yes	No

Items	IN TOUCH DIABETES Management Software	TysonBio Link Health Management System
clock to a specific date and time		
Ability to email report from PC directly from program	Yes	No
Ability to input additional information on manual result	Yes	No

I. Standard/Guidance Document Referenced (if applicable):
   None
J. Performance Characteristics:

   1. Analytical Performance:
       a. *Accuracy:*
           see above associated devices k062829, k072854 and k073492

           The accuracy of PC download feature was investigated in k073492. There is a 300 test memory capacity in DIACHEX+ INFINITY Blood Glucose Meter. The PC download feature was validated by installing the TysonBio Link Health Management System software, setting meter in PC transfer data mode and connecting to computer through RS 232 port. The accuracy of transfer data was validated by comparison to the original data in DICHEX+ INFINITY device.

       b. *Precision/Reproducibility:*
           see above associated devices k062829, k072854 and k073492
       c. *Linearity:*
           see above associated devices k062829, k072854 and k073492
       d. *Carryover:*
           Not Applicable
       e. *Interfering Substances:*
           see above associated devices k062829, k072854 and k073492

   2. Other Supportive Instrument Performance Data Not Covered Above:

       125 typical diabetic users ranging in age, education and about equally divided between males and females were included in the user study. Participants were first provided with a DIACHEX Basic or DIACHEX Superb glucose meter (with previously stored test data), cable and both the meter and software User's manuals. They were asked to read the user's

manual and follow the instructions to install the software to transfer the data from meter to PC and use all the software application functions. The statistical analysis of study participants' response to consumer questionnaire indicated the software is easy to use and met the expectation of end users.

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.