510(k) SUMMARY

AUG 2 6 2008

K081726

1. DATE PREPARED

June16, 2008

2. SPONSOR INFORMATION

Address

TYSON BIORESEARCH, INC.
5 F., # 22, KE TUNG RD., SCIENCE BASED INDUSTRIAL PARK
CHUN-NAN, MIAO-LI COUNTY, CHINA (TAIWAN) 350

Contact Person: WEN-HAI TSAI

PHONE: 886-37-585988
FACSIMILE: 886-37-585996

3. NAME OF DEVICE:

1.	Trade Name:	TysonBio Link Health Management System
2.	Common Names:	Data Management Software
3.	Classification Names :	Calculator/data processing module for clinical use, 21CFR862.2100 Glucose Test System, 21 CFR862.1345
4.	Product code:	NBW - System, test, blood glucose, over the counter, JQP - Calculator/data processing module for clinical use

4. DEVICE DESCRIPTION:

The TysonBio Health Management System software is an optional software accessory for use with TysonBio blood glucose monitors with data management capabilities. When use with one of these meters, TysonBio Link Health Management System software transfers data from the devices records into a computer for enhanced data management. It should be noted that the software does not recommend any medical treatment or medication dosage level.

5. Principles of Operation

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. It 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.

6. INTENDED USE:

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.

7. PREDICATE DEVICE:

Predicate device name(s): LifeScan IN TOUCH Diabetes Management System
Predicate 510(k) number(s): k984527

8. Comparison with predicate:

The TysonBio Link Health Management System software is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Lifescan IN TOUCH Diabetes Management software (k984527). Both management software programs can be described as follows:

- have the same intended use.
- Data transferred from the device cannot be changed or modified in any way
- An optional software accessory for use with blood glucose monitors with data management capabilities
- Do not in any way control or affect the blood glucose monitor's measurements

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

Items	IN TOUCH DIABETES Management Software	TysonBio Link Health Management System
Cable availability	Serial cable, cable available separately	Serial cable, cable available separately
Capable for uploading data from various devices	Software driver must be uploaded on the device or installed on PC	Software driver must be installed on PC
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 as
Software use indications	Home or clinic settings	Single or multiple user settings
Deleting patients and all accompanying records	Yes	Yes
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
Language capabilities	English, Spanish	English
Viewing the Owner's manual	Link provided via icon	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

Items	IN TOUCH DIABETES Management Software	TysonBio Link Health Management System
Report types	Standard Day, Average Reading, Insulin, Exception, Data List Histogram, Health checks	No Insulin, Exception, standard day report.
Ability to set meter clock to a specific date and time	Yes	No
Ability to email report from PC directly from program	Yes	No
Ability to input additional information on manual result	Yes	no

9. Performance Data

The TysonBio Health Management System software has been developed in accordance with the FDA's Guidance for Content of Premarket Submission for Software Contained in Medical Devices(May 11,2005) and general Principles of Software Validation 1/11/2002 : Final Guidance for Industry and FDA Staff, where applicable and appropriate. Software verification and validation testing demonstrated that the TysonBio Health Management System meets the performance requirements for the intended use of the optional accessory device.

10. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision. Software verification and validation testing demonstrated that the TysonBio Health Management System meets the performance requirements for the intended use of the optional accessory device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 6 2008

Tyson Bioresearch, Inc.
c/o Mr. Wen-Hai Tsai
5 F., # 22, Ke Tung Rd.
Science Based Industrial Park
Chun-Nan, Miao-Li County
China (Taiwan) 350

Re: k081726
Trade/Device Name: Tysonbio Link Health Management System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: June 16, 2008
Received: June 18, 2008

Dear Mr. Tsai:

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): K081726

Device Name: TysonBio Link Health Management System

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Prescription Use X (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)

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

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