K080960

Abbott Diabetes Care

SEP 5 2008

Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502
[illegible]

510(k) Summary
(as required by 21 CFR 807.92)

Date Prepared:	April 1, 2008
Company	Abbott Diabetes Care Inc.
Division	Abbott Diabetes Care Inc.
Street Address	1360 South Loop Road
City, State Zip	Alameda, CA 94502
Telephone No.	510-749-5400
Fax No.	510-864-4791
Contact Person:	Maria Trejo Regulatory Affairs Associate Tel No. 510-749-6384 Fax No. 510-864-4791 maria.trejo@abbott.com
Device Name:	Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System
Common Name:	Blood Glucose Test System
Classification Name:	Glucose Dehydrogenase, Glucose, Class II (21 CFR 862.1345) Ketones Test System, Ketones, Class I (21 CFR §862.1435) Product codes NBW, LFR, JIN
Predicate Device:	Precision Xtra Diabetes Monitoring System (K040814)

Description of the Device:

The Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System (BGKMS) utilizes amperometric biosensor technology to measure glucose and β-ketone in the sample found in the Precision Xceed Pro test strips to quantitatively measure glucose and β-hydroxybutyrate (β-ketone) concentrations in whole blood samples and Precision, MediSense or Optium Control Solutions.

The Precision Xceed Pro BGKMS measures glucose electrochemically. The glucose biosensor is capable of determining glucose oxidized by the enzyme (Glucose Dehydrogenase, GDH) catalysed reaction with Nicotinamide Adenine Dinucleotide (NAD^+) cofactor. The reduced form of NAD^+ (NADH) is re-oxidized by reaction with the electrochemical mediator, 1,10-phenanthroline quinone (1,10-PQ). The reduced mediator is re-oxidized via electron transfer at the electrode surface. This current is translated into a

number by the monitor, after applying lot specific calibration information and after a 20 second countdown, a concentration value is presented to the user. In this same manner, the biosensor electrode utilizes the enzyme hydroxybutyrate Dehydrogenase (HBDH), which reacts with the β-hydroxybutyrate (β-ketone) concentration in the sample. This reaction is transferred to the monitor through an electrical current generated proportional to the level of β-ketone in the sample. This current is translated into a number by the monitor, after applying lot specific calibration information and after a 10 second countdown, a concentration value is presented to the user.

Intended Use:

The Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System is intended for *in vitro* (outside the body) diagnostic use for the quantitative measurement of glucose (D-glucose) in fresh capillary, venous, arterial and neonatal whole blood samples, provided the sample is used within 30 minutes, and of β-Ketone (beta-hydroxybutyrate) in fresh capillary and venous whole blood samples. The Precision Xceed Pro System is for home (lay user) or professional use. The system is not for use in diagnosing diabetes mellitus, but is to be used as an aid in monitoring the effectiveness of diabetes control programs.

Summary of Technological Characteristics:

The Precision Xceed Pro BGKMS has the same fundamental scientific technology and the same intended use as the current on-market Precision™ Xtra System which is based on the same amperometric biosensor technology. The Precision Xceed Pro BGKMS is substantially equivalent to the current predicate device.

Assessment of Non-Clinical Performance Data:

The modified blood glucose monitoring system was tested in accordance with ISO 15197:2003. The performance of the Precision Xceed Pro BGKMS has been verified through non-clinical testing in the laboratory. Testing on dynamic range, precision, linearity, accuracy, and temperature were completed and all passed. These studies demonstrated that the Precision Xceed Pro BGKMS is substantially equivalent to the current Precision Xtra BGMS for blood glucose and β-ketone measurements and is suitable for its intended use.

Assessment of Clinical Performance Data

The modified blood glucose monitoring system was also verified through clinical fingertip studies which were conducted to evaluate the accuracy, lay user acceptability and ease of use of the Precision Xceed Pro System (BGKMS). These studies demonstrated that the Precision Xceed Pro BGKMS is substantially equivalent to the current Precision Xtra BGMS for blood glucose and β-ketone measurements and is suitable for its intended use.

Conclusion:

Results of non-clinical testing demonstrate that the performance of the Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System, when used according to the intended use stated above, is acceptable and substantially equivalent to the performance of the previously mentioned predicate device for blood glucose testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 5 2008

Abbott Diabetes Care, Inc.
c/o Ms. Tammy Wharton
Senior Regulatory Affairs Specialist
1360 South Loop Road
Alameda, CA 94502

Re: k080960
Trade Name: Precision Xceed Pro Blood Glucose and ß-Ketone Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR, JIN
Dated: August 14, 2008
Received: August 15, 2008

Dear Ms. Wharton:

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

Indications for Use

510(k) Number: K080960

Device Name: **Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System**

Indications for Use:

The Precision Xceed Pro Blood Glucose and β-Ketone Monitoring System is intended for in vitro (outside the body) diagnostic use for the quantitative measurement of glucose (D-glucose) in fresh capillary whole blood (fingertip), and of β-Ketone (beta - hydroxybutyrate) in fresh capillary whole blood samples. The Precision Xceed Pro System is for home (lay user) or professional use. The system is not for use in diagnosing diabetes mellitus, but is to be used as an aid in monitoring the effectiveness of diabetes control programs.

Healthcare professionals may also use the product for the quantitative measurement of glucose in venous, arterial, or neonatal whole blood and ketone in venous blood, provided the sample is used within 30 minutes after collection.

Prescription User ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K080960