K060768

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APR 2 1 2006

Attachment 4

510(k) Summary

(as required by 21 CFR 807.92)

Submitted by: Maria E. Trejo
Regulatory Affairs Associate
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502
510-749-6384

Date Submitted: March 21, 2006

Device Name: Precision Xtra Blood β-Ketone Test Strips
Optium Blood β-Ketone Test Strips

Common Name: Blood Ketone Test Strips

Classification: Ketone Test System
Class I per 21 CFR 862.1435

Product Code: JIN

Predicate Device: Precision Xtra Blood β-Ketone Test Strips, K983504
Optium Blood β-Ketone Test Strips, K040814

Description: The Precision® Xtra™ Diabetes Monitoring System utilizes amperometric biosensor technology to generate a current. The size of the current is proportional to the amount of β-hydroxybutyrate (β-ketone) present in the sample, providing a quantitative measure of β-ketone in whole blood and control solutions.

Intended Use: The Precision Xtra Blood β-Ketone Test Strips are intended for *in vitro* diagnostic use (i.e., external use only) for the quantitative measurement of β-hydroxybutyrate (β-ketone) in fresh capillary

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whole blood. The Precision Xtra Blood β-Ketone Test Strips are indicated for home (lay user) or professional use. Healthcare professionals may also use venous whole blood samples, provided the samples are used within 30 minutes of collection.

Comparison to Predicate Device: The Precision Xtra Blood β-Ketone Test Strips/ Optium Blood β-Ketone Test Strips use the same fundamental scientific technology and have the same intended use as the predicate Precision Xtra Blood β-Ketone Test Strips (K983504) and Optium Blood β-Ketone Test Strips (K050814).

Performance Studies: The performance of the Precision Xtra Blood β-Ketone Test Strips was verified through non clinical testing in the laboratory. The studies demonstrated that the Precision Xtra Blood β-Ketone Test Strips/ Optium Blood β-Ketone Test Strips are substantially equivalent to the current Precision Xtra Blood β-Ketone Test Strips/ Optium Blood β-Ketone Test Strips for blood β-ketone measurements.

Conclusion: Results of non clinical testing demonstrate that the performance of the Precision Xtra Blood β-Ketone Test Strips/ Optium Blood β-Ketone Test Strips, when used according to the intended use stated above, are acceptable and comparable to the performance of the previously mentioned predicate device for β-ketone testing.

Test performed and passed were altitude, dynamic range, precision, linearity, accuracy, sample volume, interference, sensor movement, oxygen sensitivity, sample application (end/top fill), environmental, haematocrit, PH and shipping.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Maria E. Trejo
Regulatory Affairs Associate
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502

APR 2 1 2006

Re: k060768
Trade/Device Name: Precision Xtra Blood β-Ketone Test Strips
Optium Blood β-Ketone Test Strips
Regulation Number: 21 CFR§862.1435
Regulation Name: Ketones (nonquantitative) test system
Regulatory Class: Class I
Product Code: JIN
Dated: March 21, 2006
Received: March 22, 2006

Dear Ms. Trejo:

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) 276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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 (if known): K060768

Device Name: Precision Xtra Blood β-Ketone Test Strips
Optium Blood β-Ketone Test Strips

Indications For Use:

The Precision Xtra / Optium Blood β-Ketone Test Strips are intended to quantitatively measure blood β-Ketone (Beta-Hydroxybutyrate) in fresh capillary whole blood from the fingertip. The test strips are for use outside the body (*in vitro* diagnostic use) and are for self-testing or healthcare professional use. Healthcare professionals may also use venous whole blood samples, provided the samples are used within 30 minutes of collection. The test strip is to be used for ketone concentrations in persons with diabetes and other conditions.

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

Office of In Vitro Diagn
Evaluation and

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