K063068

5 510(k) Summary

DEC 2 0 2006

Submitter:	Arkray USA
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Date Prepared:	October 3, 2006
Trade Name:	Ferrara Blood Glucose Monitoring System
Classification:	Glucose test system, 21 CFR 862.1345; Class II
Product Codes:	CGA, NBW
Predicate Devices:	Advance Micro-draw BGM Assure Pro BGM
Device Description:	The Ferrara Blood Glucose Monitoring System consists of a meter, test strips, and control solution. It is intended for over-the-counter, home use by diabetics to monitor their blood glucose levels, or for use in a clinical setting by health care professionals. The system tests fresh capillary whole blood. The meter is a portable, battery-operated instrument designed for use with Ferrara Blood Glucose Test Strips.
Intended Use:	The Ferrara Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or palm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.
Functional and Safety Testing:	SUMMARY OF TECHNOLOGICAL CHARACTERISTICS The Ferrara Blood Glucose Monitoring System is technically unchanged by this expansion of indications (claiming palm as sample sites in addition to fingertip testing). The Ferrara system uses a meter substantially equivalent to the "Advance™ Micro-draw" meter with a test strip SE to the Assure Pro test strip.

1. NON-CLINICAL TESTING

Not Applicable

2. CLINICAL TESTING

Accuracy/method comparison testing was done comparing fingertip results obtained by clinicians with alternate site results (palm) results obtained by participants with diabetes.

Testing included both men and women, with both Type 1 and Type 2 diabetes, ages from 20 to 83 years. Tested blood glucose values encompassed the 45-328 mg/dL glucose range. Linear regression statistics, Clarke Error Grid Analysis, and Bias Analysis showed good correlation between fingertip and alternate site results.

Conclusion: Testing demonstrated that the performance of Ferrara at the palm alternate site was substantially equivalent to that at fingertip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Tom Speikers
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Re: k063068
Trade/Device Name: Ferrara Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: October 03, 2006
Received: October 06, 2006

Dear Mr. Speikers,

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper, MS, D.V.M.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

4 Indications for Use Statement

510(k) Number (if known): K063068

Device Name: Ferrara Blood Glucose Monitoring System

Indications For Use:

Ferrara Blood Glucose Monitoring System:

The Ferrara Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or palm. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Ferrara Blood Glucose Test Strips:

Ferrara Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or palm. Ferrara Test Strips must be used with the Ferrara Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Ferrara Control Solution:

For use with Ferrara Blood Glucose Meter and Ferrara Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use _____ (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 OF NEEDED)

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

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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