5. 510(k) SUMMARY (k083273)

5.1 Purpose for Submission:
Modification and addition to existing product.

5.2 Analyte:
Whole blood Glucose

NOV 19 2009

5.3 Type of Test:
Quantitative (electrochemical biosensor)

5.4 Applicant:
Cambridge Sensors Limited

Units 9 & 10
Cardinal Park
Godmanchester
Huntingdon
Cambs PE29 2XG
United Kingdom

5.5 Proprietary and names:
microdot® Xtra Blood Glucose Monitoring system : blood glucose monitor consisting of three products
- ***microdot***® Xtra Blood Glucose Meter
- ***microdot***® Xtra Test Strips
- ***microdot***® Control solutions

5.6 Regulatory Information:
1. Regulation section:
   21 CFR § 862.1345, Blood Glucose Test System
   21 CFR § 862. 1660, quality control material (assayed and un-assayed)

2. Classification:
   Class II, Class I

3. Product Code:
   NBW, Blood Glucose test system, over the counter
   LFR, Glucose Dehydrogenase, glucose
   JJX, Single (specified) analyte controls (assayed and unassayed)

4. Panel:
   Clinical chemistry (75)

5.7 Intended Use

Intended use(s):

microdot® Xtra Blood Glucose Monitoring System

microdot® Xtra Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick. It is intended for use by persons with diabetes or by health care professionals in home settings or healthcare facilities.

indication(s) for use:

microdot ® Xtra Blood Glucose Monitoring System is intended for self testing of glucose in capillary whole blood from a fingerstick by persons with diabetes or by health care professionals in home settings or healthcare facilities. It is not intended for use on neonates or in the diagnosis of or screening for diabetes mellitus.

microdot® Xtra Blood Glucose Meter
The ***microdot***® Xtra Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick. It is intended for use by persons with diabetes or by health care professionals in home settings or healthcare facilities.

microdot® Xtra Test Strips
The ***microdot***® Xtra Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick. It is intended for use by persons with diabetes or by health care professionals in home settings or healthcare facilities.

microdot® Control solutions
The ***microdot***® Control solutions are intended for use with ***microdot***® Xtra Blood Glucose Meter and ***microdot***® Xtra Test Strips as a quality control check to verify the accuracy of the blood glucose test results.

Special conditions for use statements(s):

This product is intended for over-the-counter and point-of-care use.
Special instrument requirements:

microdot® Blood Glucose Meter

5.8 Device Description:

The ***microdot***® Xtra Blood Glucose Monitoring System consists of the ***microdot***® Xtra Blood Glucose Meter, ***microdot***® Xtra Test Strips, ***microdot***® Control Solutions and a commercially available (510(k) cleared) lancing device and lancets.

The ***microdot***® Xtra Blood Glucose Monitoring System is intended for invitro diagnostic use and for the quantitative measurement of glucose in fresh capillary whole blood. The modified device ie ***microdot***® Xtra Blood Glucose Monitoring System, and its predicate device, ***microdot***® Blood Glucose Monitoring System are intended for use by persons with diabetes or by healthcare professionals in home settings or healthcare facilities.

The modified ***microdot***® Xtra Blood Glucose Monitoring System is substantially equivalent in form, firmware, fundamental scientific technology and specifications as the predicate system. The ***microdot***® Xtra Blood Glucose Monitoring System relies on quantitative electrochemical biosensor technology to measure current generated on disposable test strips.

The strip remains unchanged since the last submission approval, ***microdot***® Blood Glucose Monitoring System (k070524). The Test Strip manufacturing and performance characteristics are unchanged. The test strips are designed to quantitatively measure glucose in fresh capillary blood from the fingertip by persons with diabetes or by healthcare professional in home or healthcare facilities. Both the predicate strips, ***microdot***® Test Strips (k070524) and the ***microdot***® Xtra Test Strips use the reagent glucose dehydrogenase with nicotinamide-adenine dinucleotide as co-factor.

The predicate meter uses lot specific calibration code number marked on the strip vial label. The specific code number on the strip vial label allows the meter to convert electrical current into glucose readings via the embedded software in the meter. The user calibrates their meter each time they open a new vial of strips.

Each lot of strips is calibrated to give plasma equivalent glucose readings. The meter is turned on by strip insertion, the user applies a drop of blood or control solution to the test strip and the meter starts the measurement. After 10 seconds, the meter displays the glucose concentration and time and date on the LCD display.

The ***microdot***® Xtra Blood Glucose Monitoring System is pre-programmed with a predetermined code number, thus removing the requirement to load a code number specific to the strip vial.

5.9 Substantial Equivalence Information:

Predicate device name (s):

microdot® Blood Glucose Monitoring System

Predicate 510(k) number: k070524

Comparison with predicate:

microdot® and ***microdot***® Xtra Test Strips share the same design, functionality, raw materials and manufacturing process.

Comparison to Predicate Device:

Product Name	***microdot***® Xtra	***microdot***® (K070524)
Characteristic/aspect	***Auto Code System***	***Code entered according to new value on strip vial***
Intended Use	Blood glucose monitoring for home and point of care	Same
Sample	Fresh Capillary whole blood	Same
Test Principle	Electrochemical Biosensor	Same
Calibration	Plasma equivalent	Same
Sample volume	600nanoliters	Same
Temperature and humidity range	10°- 40°C 10-90% RH	Same
Control Solutions Color Fill Volume Matrix	3 levels Blue 4 ml Buffered aqueous solution of D-glucose, viscosity modifier, preservatives and other, non-reactive ingredients	Same
Stability	Strips and controls, 3 months after opening	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Cambridge Sensors Limited
c/o Ms. Bernadette Yon-Hin
Units 9 & 10 Cardinal Park
Godmanchester
Huntingdon, Cambridgeshire
United Kingdom PE29 2XG

NOV 19 2009

Re: k083273
Trade Name: Microdot® Xtra Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Blood Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: October 5, 2009
Received: October 9, 2009

Dear Ms. Yon-Hin:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
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): (k083273)

Device Name: ***microdot*** Xtra® Blood Glucose Monitoring System

microdot Xtra® Blood Glucose Monitoring System

The ***microdot*** Xtra ® Blood Glucose Monitoring System is intended for self test use outside the body (*in vitro* diagnostic use only). It should be used only for testing fresh capillary whole blood samples from a fingerstick for glucose (sugar). It is not intended for use on neonates or in the diagnosis of or screening for diabetes mellitus.

indication(s) for use:

microdot Xtra ® Blood Glucose Monitoring System

The ***microdot*** Xtra ® Blood Glucose Monitoring System is intended for self testing of glucose in capillary whole blood from a fingerstick by persons with diabetes or by health care professionals in home settings or healthcare facilities.

microdot Xtra ® Blood Glucose Meter

The ***microdot*** Xtra ® Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick. It is intended for use by persons with diabetes or by health care professionals in home settings or healthcare facilities.

microdot Xtra ® Test Strips

The ***microdot*** Xtra ® Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick. It is intended for use by persons with diabetes or by health care professionals in home settings or healthcare facilities.

microdot® Control solutions

The ***microdot***® Control solutions are intended for use with ***microdot*** Xtra ® Blood Glucose Meter and ***microdot*** Xtra ® Test Strips as a quality control check to verify the accuracy of the blood glucose test results.

Prescription Use _____ And/Or Over the Counter Use **YES**
(21 CFR Part 801 Subpart D) (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

510(k) k083273