510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k083273

B. Purpose for Submission:

Modification of predicate meter that required coding to new auto code meter in which there is one pre-programmed code.

D. Type of Test:

Quantitative (glucose oxidase)

E. Applicant:

Cambridge Sensors Limited

F. Proprietary and Established Names:

microdot Xtra Blood Glucose Meter

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345 Glucose Test System
   21 CFR 862.1660 Quality control material (assayed and unassayed)

2. Classification

   Class II – Glucose

   Class I - Controls

3. Product code:
   NBW – System, Test, Blood Glucose, Over the Counter
   CGA – Glucose Oxidase, Glucose
   JJX --Single analyte control (assayed and unassayed)

4. Panel:

   75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for use below

2. Indication(s) for use:
   The microdot Xtra Blood Glucose Monitoring System is intended for self testing of glucose in capillary whole blood by persons with diabetes or by health care professionals in home settings or healthcare facilities. It is intended for monitoring of blood glucose levels only. It is intended 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. It is intended for monitoring of blood glucose levels only.

   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. It is intended for monitoring of blood glucose levels only.

   microdot Control Solutions

   microdot Control Solutions are intended for use with the 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

3. Special conditions for use statement(s):
   For over the counter use.

   Not intended for the diagnosis of or screening for diabetes and not intended for use on neonates. The device should not be used for patients who are dehydrated, in shock, critically ill or in a hyperosmolar state.

4. Special instrument requirements:

   microdot Xtra Glucose Meter

I. Device Description:

The microdot Xtra Blood Glucose Monitoring System consists of the microdot Blood Glucose Meter, microdot Xtra Test Strips, microdot Xtra Control Solutions and a commercially available lancing device and lancets.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   microdot Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
   k070524
3. Comparison with predicate:
   The modified device has the same performance characteristics as the predicate. The difference is the new device is an auto code meter and the test strip port has been modified to accommodate the microdot Xtra test strip.

K. Standard/Guidance Document Referenced (if applicable):

CLSI Guideline EP6-A – Evaluation of the linearity of Quantitative Analytical Methods

L. Test Principle:

The test is base on the enzymatic conversion of glucose. Glucose dehydrogenase converts glucose in the sample to gluconolactone, with concomitant reduction of the enzyme cofactor NAD+ to NADH. The NADH is re-oxidised to NAD+ by the mediator compound which in turn becomes reduced; re-oxidation of the mediator by the meter induces a micro current to flow, and the size of this micro current is directly proportional to the amount of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Precision and reproducibility were evaluated in k070524

   b. Linearity/assay reportable range:

   Linearity was evaluated in k070524

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The controls supplied with this device were cleared under k070524.

d. *Detection limit:*

The detection limit of the microdot Xtra is 20 mg/dL, and was evaluated in k075024.

e. *Analytical specificity:*

Specificity was evaluated in k070524.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Method comparison studies were evaluated in k070524

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable

b. *Clinical specificity:*

Not applicable

c. *Other clinical supportive data (when a. and b. are not applicable):*

Not applicable

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   The expected blood glucose values for people without diabetes[1]:

   Time Range, mg/dL
   Before meals 70-105
   1 hour after meals Less than 160
   2 hours after meals Less than 120
   Between 2 and 4 a.m. Greater than 70

   [1]Beaser, R.S. and Hill, Joan: The Joslin Guide to Diabetes, New York: Simon and Schuster (2005).

N. Instrument Name:

Microdot Xtra Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for each additional reading.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes __X_____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   This device is intended to be used with capillary whole blood from the finger only. Since the whole blood sample is applied directly to the test strip, there are no special handling

or storage issues.

5. Calibration:

   Calibration is factory set by the manufacturer. No coding by the user is required.

6. Quality Control:

   One control level is provided with the device. Two additional control levels are available from authorized distributors. The user is instructed to run controls when the meter is first used in order to verify that they can use the meter correctly. In addition they are instructed to run a control when a new vial of test strips is opened, at least once a week, when they suspect the meter or strips are not working correctly, when test results are not consistent with the patient's symptoms or the patient does not think the results are accurate, or if the meter is dropped. The acceptable results ranges are shown on the test strip vial label. If the results are outside the expected range, the user is instructed to repeat the test. If the results continue to fall outside the expected range, the user is instructed to call customer service.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

The new device is a modification of predicate meter that required coding, to a new auto code meter in which there is one pre-programmed code. The sponsor indicated the microdot xtra test strip is identical in composition and manufacture to the microdot test strip and only lots of microdot test strips that have a specific calibration curve are designated as the microdot xtra test strip. The unique calibration curve is determined through the QC release process which utilizes a library of multiple calibration codes. The qualification plan for the new auto code meter which included documentation of design inputs, risk analysis, design output, test procedures, verification and validation procedures, and documentation of formal design reviews was reviewed and found to be acceptable.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.