510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k033860

B. Purpose of the Submission:
New device

C. Analyte:
Hydroxybutyric Acid

D. Type of Test:
Calibrator

E. Applicant:
Wako Chemicals, USA, Inc.

F. Proprietary and Established Names:
Wako Total Ketone Body Calibrators

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1150, Calibrators, Secondary

2. Classification:
   II

3. Product Code:
   JIT

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   Refer to Indications for use.

2. Indication(s) for use:
   The Wako Total Ketone Body Calibrators are intended to be used with the Wako Total Ketone Bodies and the Wako Autokit 3-HB test kits to establish points of reference that are used in the determination of values in the measurement of total ketone bodies and 3-HB in human serum or plasma.

(Reviewer Note: 3-HB is a common abbreviation for 3 -Hydroxybutyrate.)

3. Special condition for use statement(s):
   The calibrators are for Rx in vitro diagnostic use.

4. Special instrument requirements:
   Wako 30R®

I. Device Description:

The products consist of two levels of liquid ready to use calibrators. They consist of a matrix of Goods Buffer, polyethylene glycol and sodium azide and are prepared by adding 3-Hydroxybutyrate.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Stanbio Standard, 1 mM Sodium D-3-Hydroxybutyrate (Formerly GDS)
2. Predicate K number(s):
   k910108
3. Comparison with predicate:
   Both are liquid based calibrators intended to provide reference points for ketone assays. They are intended to calibrate different assays made by different manufacturers.

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

The sponsor did not reference any standards in their submission.

L. Test Principle: Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Not applicable.

   b. *Linearity/assay reportable range:*
      Not applicable.

   c. *Traceability (controls, calibrators, or method):*

      There are two levels of calibrators:
      40 µmol/L and 300µmol/L of 3-Hydroxybutyrate.

      Calibrators are prepared by adding 3-Hydroxybuturate to buffer.
      The grade of chemicals utilized was not specified.

      The value assignment and traceability is provided through use of the molar extinction coefficient (K-factor) of NADH.

Results from Real Time Stability studies are summarized. The calibrators were evaluated for up to 15 months when stored at 10 degrees C and were both levels were within 1% of the expected value at all measurement times.

d. Detection limit:
Not applicable.

e. Analytical specificity:
Not applicable.

f. Assay cut-off:
Not applicable.

2. Comparison studies:
   a. Method comparison with predicate device:
   Not applicable.

   b. Matrix comparison:
   Not applicable.

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   b. Clinical specificity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   Not applicable.

N. Conclusion:

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