SPECIAL 510(K): DEVICE MODIFICATION
OIR DECISION MEMORANDUM

510(k) Number: K181436

This 510(k) submission contains information/data on modifications made to the applicant's own class II or class I devices requiring 510(k). The following items are present and acceptable:

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1. The name and 510(k) number of the applicant's previously cleared device. (For a preamendment device, a statement to this effect has been provided.)

   OSOM Mono Test

   510(k) number: K972231

2. Applicant's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S):**

   This change was for a modification of the OSOM Mono Test whereby the current capillary tube, which includes a Mylar wrapped glass tube and a dry natural rubber latex bulb, will be replaced by the Microsafe capillary tube. Both the current capillary tube and the Microsafe capillary tube collect 50 µL of fingertip whole blood and deliver the blood to the sample Test Tube. No changes to the chemistry of the assay have been made as the unmodified and modified devices are identical in assay formulation.

   The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and assay information:

Similarities

	Proposed: **SD OSOM Mono Test**	**Predicate:** **SD OSOM Mono Test, K972231**
Intended Use	Same	The OSOM Mono Test is intended for the qualitative detection of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aid in the diagnosis of infectious mononucleosis.
Qualitative	Same	Yes
Read Results	Same	5 minutes
Test Principle	Same	Immunochromatographic Device
Format	Same	Lateral Flow
Antibodies Used	Same	Bovine erythrocyte extract
Specimen Types	Same	Serum, Plasma and whole blood
Sample Volume	Same	50-55 µL
Read Result Time	Same	5 minutes
External Controls	Same	Mono Positive and Negative Controls provided in the kit. Internal procedural control

Differences

	Proposed: **SD OSOM Mono Test**	**Predicate:** **SD OSOM Mono Test, K972231**
Fingertip whole blood collection device	Microsafe is a one-piece single use plastic capillary pipette	Capillary Tubes (Mylar wrapped glass tubes) with 1 Capillary Bulb (contains dry natural rubber)
Labeling - IFU	**Proposed:** **Kit Contents and storage:** 25 Capillary Pipettes Note: Extra components (tubes, pipettes, capillary pipettes) have been provided for your convenience.	**Predicate:** **Kit Contents and storage:** 25 Capillary Tubes with 1 Capillary Bulb Note: Extra components (tubes, pipettes, capillary tubes, capillary bulb) have been provided for your convenience.
	Proposed: **WARNINGS AND PRECAUTIONS** For hazards and precautions, refer to the safety data sheet. • Caution: Federal Law restricts sale of this device to or on the order of a licensed practitioner. • For in-vitro diagnostic use only.	**WARNINGS AND PRECAUTIONS** **Warning** H317: May cause an allergic skin reaction. P280: Wear protective gloves/protective clothing/eye protection/face protection. • For in-vitro diagnostic use only.

	Proposed: **SD OSOM Mono Test**	**Predicate:** **SD OSOM Mono Test, K972231**
	• Follow your laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens. • The Diluent and Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. For sites permitted to dispose of material down a sink: large quantities of water must be used to flush discarded control material down a sink. • Do not interchange or mix components from different kit lots.	• Follow your laboratory safety guidelines in the collection, handling, storage and disposal of patient specimens and all items exposed to patient specimens. • The Diluent and Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. For sites permitted to dispose of material down a sink: large quantities of water must be used to flush discarded control material down a sink. • The Capillary Bulb contains dry natural rubber. • Do not interchange or mix components from different kit lots.
	Proposed: **Specimen Collection and Preparation:** Fingertip Whole Blood Hold the capillary pipette horizontally, and touch the tip of the pipette to the drop of blood on the patient's finger until it fills completely. Note: Filling is automatic; never squeeze the pipette bulb while collecting sample.	**Specimen Collection and Preparation:** Fingertip Whole Blood Hold the capillary tube horizontally while collecting the sample. Holding the capillary tube near the red circle, touch the other end of the capillary tube to the drop of blood on the patient's finger. Fill the capillary tube completely. Place the small end of the black bulb onto the capillary tube. Place your fingertip over the opening in the bulb. Squeeze the bulb to dispense the whole blood sample into the test tube.
Picture of micropipette		

5. A **Design Control Activities Summary**:

   A risk assessment of the modified Mono Test was conducted and documented according to the firm's Quality Systems requirements. This assessment included a standard Failure Mode and Effects Analysis (FMEA) which concluded that there is minimal impact on Clinical Studies and that the only risk was to Non-Clinical Performance. Two studies were carried out to demonstrate that there was no impact on the results with the modified assay – Volume Capability Study and Compatibility Study.

   i. Volume Capability Study: The volume of deionized water taken up by the Micrsafe Tubes when following the package insert was measured using three lots of Microsafe Tubes. The average volume within and across lots was between 50 µL and 55 µL and met the acceptance criteria.
   ii. Compatibility Study: Finger-stick samples from three different seronegative donors were evaluated across the three lots of Microsafe Tubes. No deleterious effect on the assay was observed and the results met the acceptance criteria.

   A third study (Time to Dispense) was carried out to determine how long a finger-stick sample could be retained in a MicroSafe Tube and still be dispensed. The study was for information only.

   iii. Finger-stick whole blood samples were collected and dispensed after 30, 60, and 120 seconds. Three lots of Microsafe Tubes were evaluated. A finger-stick sample could be left in the Microsafe Tube for 120 seconds with no deleterious effect on dispensing a specimen.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the applicant's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The applicant has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.