

AUG 14 1996

5

K955719

510(K) SUMMARY for SICKLE-2000

Submitted by: Medicus Technologies, Inc.
515 S. Franklin St.
West Chester, PA 19382
Telephone # is 610-692-5711
Fax # is 610-692-1913
Registration # 2518629

1. Product name: The trade name is SICKLE-2000. The common name is Sickle cell test or Sickle cell Hb solubility test.
2. This is a class II device(21 CFR 864.7825, Sickle cell test).
3. Description: SICKLE-2000 is an in-vitro centrifugal solubility test that detects Hemoglobin S, the abnormal hemoglobin found in sickle cell disease and sickle cell trait.
4. Product equivalency: The predicate device most like SICKLE-2000 is Sicklequik(Organon Teknika, Durham,NC). The only difference is that mineral oil is a component of the SICKLE-2000 reagent and toluene is a component of the Sicklequik reagent. Sicklequik is a pre-amendment device.
5. The clinical performance of this test was determined in two different studies. One study compared SICKLE-2000 to Sicklequik. Blood samples were added to both Sicklequik and SICKLE-2000 tubes and the results compared. Eighty seven patients were tested. 66 contained no hemoglobin S. 15 were heterozygous (AS), and 6 homozygous (SS). In each instance the results were the same.

In a blind study 59 normal samples and 40 heterozygous S samples that had previously been tested by hemoglobin electrophoresis were tested by SICKLE-2000. SICKLE-2000 correctly identified each sample.

6. Additional studies conducted include accelerated aging, real time stability, the determination of the lowest concentration of hemoglobin S that can be detected, and potential interfering substances.
 - 6.1 Accelerated aging was done on three batches, each made with a different lot of mineral oil. Arrhenius plotting indicated no significant change in sodium bisulfite or saponin activity over a two year time period.
 - 6.2 Real time stability studies indicate the product is good for at least 12 months. Expiration dating will be based on real time stability studies.
 - 6.3 The lowest concentration of hemoglobin S that can be detected was determined using 10 heterozygous S samples. This concentration is 2.0g/dl hemoglobin S.
 - 6.4 The potential interfering effects of lipemia, bilirubin and hemolysis were studied. There is no triglyceride interference up

to 1000mg/dl. Hemolysis does not interfere. With normal(AA) blood there is no interference up to 60mg/dl bilirubin. With homozygous(SS) blood there is no interference up to 60mg/dl bilirubin. The lower aqueous phase which is normally yellow, simply gets more yellow with additional bilirubin. With heterozygous(AS) blood there is no interference up to 15mg/dl bilirubin. At 30 mg/dl bilirubin the aqueous phase has an orange and slightly darker appearance. At 60mg/dl bilirubin it is more orange and darker.

7. The conclusion drawn from the above studies is that the device is safe, effective, and performs as well as the predicate device Sicklequik.