

K964988

h)

**510(k) Summary**  
**COULTER® A<sup>c</sup>T Series Analyzer**

MAR - 6 1997

Date of Summary: December 10, 1996

Company/Institution name: Coulter Corporation,  
11800 SW 147 Ave.  
Miami, FL 33196, Mailcode 31-B06

Contact Name: Thomas J. English, Phone 1-305-380-4331

Common or usual name or classification name: Automated Cell Counter and Automated Differential Cell Counter

Product name: COULTER® A<sup>c</sup>T Series Analyzer  
C.F.R. Section: 864.5200 and 864.5220  
Device Class: Class II

510(k) numbers of Coulter devices to which substantial equivalence is claimed:  
COULTER® COUNTER® S-PLUS IV and LYSE S PLUS D, K823355.

The product is a hematology Automated Cell Counter and Automated Differential Cell Counter which like the predicate device, COULTER® COUNTER® S-PLUS IV and LYSE S PLUS D, uses the Coulter method of impedance measurement for particle counting and sizing. Blood cells passing through a small opening simultaneously with an electric current cause an impedance change in the orifice. This electrical pulse can be sized and counted. While the number of pulses indicates the particle count, the size of the electrical pulse is proportional to cell volume.

Under the controlled condition of lysis, a chemical reaction demonstrates one distinct population of leukocytes: lymphocytes. Mature normal lymphocytes and variant atypical lymphocytes are the smallest of the WBC cells, and tend to occupy the size range from 35 to 90 fL.

**Intended Use:** The COULTER® A<sup>c</sup>T Series Analyzers are quantitative, automated hematology analyzers. The A<sup>c</sup>T 10 Series is also a leukocyte differential counter. Both instruments are For In Vitro Diagnostic Use in clinical laboratories.

The COULTER® A<sup>c</sup>T Series Analyzers have the same intended use as the predicate device. Both the A<sup>c</sup>T Series and the predicate device utilize the Coulter principle for cell counting and sizing in combination with automatic diluting and mixing for sample processing and a beam photometer for hemoglobinometry. The same reagent system, consisting of isotonic diluent, lytic reagent, and cleaning agent, is used on both systems. Both the A<sup>c</sup>T Series and the predicate device have the ability to print and transmit results if the instrument has been setup to do. Like the predicate device, the COULTER® A<sup>c</sup>T Series Analyzers determine the following parameters WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, and Plt. The A<sup>c</sup>T 10 Analyzer determines LY # and LY %. Unlike the predicate device the A<sup>c</sup>T Series Analyzers do not measure MPV and RDW and Monocyte and Granulocyte number and percent. Unlike the predicate device the A<sup>c</sup>T Series Analyzers operate in two sample modes: Whole Blood Mode and Predilute Mode.

Testing included in this submission focuses on attributes of precision, accuracy linearity and carryover. Testing met all acceptance criteria