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510(k) Summary
COULTER® GEN·S™ System

Date of Summary: July 30, 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 Differential Cell Counter

Product name: COULTER® GEN·S™ System

C.F.R. Section: 864.5220

Device Class: Class II

Optional Device Name: COULTER GEN·S SM™ INTEGRATED SLIDEMAKER Option

C.F.R. Section: 864.5850

Device Class: Class I, Exempt

510(k) numbers of Coulter devices to which substantial equivalence is claimed:
COULTER® STKS Analyzer with Reticulocyte Analysis, K885093 and K932030

The product is an Automated Differential Cell Counter which like the predicate device COULTER® STKS Analyzer with Reticulocyte Analysis 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 particle count, the size of the electrical pulse is proportional to the cell volume.

WBC differential analysis and classification occurs in the flow cell where low-frequency current measures volume, high-frequency current senses cellular internal content, and light from the laser bouncing off the individual WBC cells characterizes cellular surface, shape and reflectivity.

To measure the number of Reticulocytes in the sample, a supravital dye, New Methylene Blue, is incubated with whole blood samples. The dye precipitates the basophilic RNA network found in reticulocytes. Hemoglobin and unbound stain are removed by adding a clearing reagent, leaving clear spherical mature RBCs and darkly stained reticulocytes. Stained Reticulocytes are differentiated from mature red cells and other cell populations by light scatter, direct current measurements and opacity characteristics when using the GEN·S with volume, conductivity, light scatter and reticulocyte counting technology.

Intended Use: The COULTER® GEN·S system is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The GEN·S System also provides automated Reticulocyte analysis. The COULTER GEN·S SM™ INTEGRATED SLIDEMAKER Option prepares a blood film on a clean microscope slide.

The GEN·S System has the same intended use as the predicate device and measures the same hematological parameters. Both systems utilize the Coulter principle for enumeration and sizing of blood cells, in combination with automatic diluting and mixing for sample processing and a beam photometer for hemoglobinometry. The same reagent system is used consisting of an isotonic diluent, lytic reagents and instrument cleaner. Both systems measure Reticulocytes utilizing New Methylene Blue. For reticulocyte analysis on the GEN·S System, a portion of aspirated sample is used for on-line preparation. Sample preparation for reticulocyte analysis on the STKS Analyzer is done off-line.

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

i) Not applicable for this submission.