

K 962426

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510(k) Summary

Device: Chrono-log Whole Blood Aggregometer (WBA), Model 591/592

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Submitted by: Chrono-log Corp., 2 West Park Rd., Havertown, PA 19083

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Name of Device:

Trade/Proprietary Name - Chrono-log Whole Blood Aggregometer (WBA), Model 591/592

Common/Usual Name - Chrono-log Whole Blood Aggregometer

Classification Name - System, Automatic Platelet Aggregation

After examining the tests data included in this application, we have found the Chrono-log Whole Blood Aggregometer (WBA), Model 591/592 to be substantially equivalent to Chrono-log Whole Blood Aggregometer (K830749) and Centocor AggreStat (K954997).

Device Description:

The Chrono-log WBA, Model 591/592 uses electrical impedance to measure platelet aggregation in a whole blood sample. The Impedance is measured using an electrode with two platinum alloy wires. A small voltage is applied across these two wires. When the electrode is placed into a diluted whole blood specimen and a monolayer is formed around the two wires. In the absence of an agonist, the platelet build-up stabilizes and a baseline is established. When an agonist is added to the specimen, the platelets begin to aggregate and collect on the electrode wires causing a change in impedance. The change of impedance is directly proportional to the amount of Aggregation in the specimen. The change of impedance is displayed on a front panel readout. An analog output which, when connected to a strip chart recorder, provides an aggregation curve. Model 591 is a single channel version; Model 592 is the dual channel version.

Intended Use:

The Chrono-log WBA, Model 591/592 is intended for determination of platelet function in a whole blood specimen.