

**SECTION 3**  
**quantex IgM - 510(k) SUMMARY**  
**(Summary of Safety and Effectiveness)**

**Submitted by:**

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**Name of the device:**

quantex IgM:	8 x 6 mL anti-human IgM	P/N 3000-22135
	2 x 100 mL Buffer	P/N 3000-22130

**Classification name(s):**

866.5510 Immunoglobulins A, G, M, D and E immunological test systems Class II

**Identification of predicate device(s):**

IL Test™ IgM #K920008/B

**Description of the device/intended use(s):**

This product permits the quantitative *in vitro* diagnostic determination of Immunoglobulin M in serum and plasma on the ILab Clinical Chemistry System by turbidimetric immunoassay method. Measurement of IgM aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

**Statement of how the Technological Characteristics of the Device compare to the Predicate device:**

Biokit's quantex IgM is substantially equivalent in performance, intended use, safety and effectiveness to the predicate, IL Test™ IgM -- 510(k) #K920008/B.

**Summary of Performance Data:**

A comparative performance study was performed with IL Test™ IgM on a Monarch Clinical Chemistry System and Biokit's quantex IgM on an ILab Clinical Chemistry System. Method comparison studies evaluated IgM levels of forty-eight serum samples on the respective instruments. The correlation (*r*) in these studies was 0.9912.