

K161522 LIAISON EBV IgM Serum Control SetJun 30, 2016
28 days to decisionK161522 · Product code: **JJX** · Microbiology
Source: <https://www.510kdatabase.net/k161522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jun 2, 2016
Decision date	Jun 30, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DiaSorin, Inc.
Location	Ellicott City, MD, US
Contact	John Walter
510(k) history	70 submissions · 69 cleared · 1998-2025

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