

**K202755 Simplexa Congenital CMV Direct and Simplexa
Congenital CMV Positive Control Pack**Nov 5, 2022
775 days to decisionK202755 · Product code: **QDZ** · Microbiology
Source: <https://www.510kdatabase.net/k202755/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Qualitative Cytomegalovirus Nucleic Acid-based Detection Device For Congenital Cytomegalovirus Infection (QDZ)
Date received	Sep 21, 2020
Decision date	Nov 5, 2022
Days to decision	775 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diasorin Molecular, LLC
Location	Cypress, CA, US
Contact	Sharon Young
510(k) history	13 submissions · 12 cleared · 2018-2025

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