

K201049 FINDER G6PDSep 14, 2022
876 days to decisionK201049 · Product code: **JBF** · Hematology
Source: <https://www.510kdatabase.net/k201049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose-6-phosphate Dehydrogenase (erythrocytic), Screening (JBF)
Date received	Apr 21, 2020
Decision date	Sep 14, 2022
Days to decision	876 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Baebies, Inc.
Location	Durham, NC, US
Contact	Ailen Gillette
510(k) history	2 submissions · 1 cleared · 2017-2022

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