

K231776 Cell-Free DNA BCTJul 26, 2024
406 days to decisionK231776 · Product code: **QMA** · Chemistry
Source: <https://www.510kdatabase.net/k231776/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Collection Device For Cell-free Nucleic Acid (QMA)
Date received	Jun 16, 2023
Decision date	Jul 26, 2024
Days to decision	406 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Streck, Inc.
Location	La Vista, NE, US
Contact	Wendy Royalty
510(k) history	3 submissions · 2 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231776/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026