

K152343 Direct BilirubinFeb 16, 2016
181 days to decisionK152343 · Product code: **JFM** · Chemistry
Source: <https://www.510kdatabase.net/k152343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Bilirubin (JFM)
Date received	Aug 19, 2015
Decision date	Feb 16, 2016
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radox Laboratories Limited
Location	Crumlin, GB
Contact	PAULINE ARMSTRONG
510(k) history	18 submissions · 18 cleared · 2004-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152343/> 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 24, 2026