

K152344 Total BilirubinJan 28, 2016
162 days to decisionK152344 · Product code: **JFM** · Chemistry
Source: <https://www.510kdatabase.net/k152344/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Bilirubin (JFM)
Date received	Aug 19, 2015
Decision date	Jan 28, 2016
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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