

K100853 COBAS 8000 MODULAR SERIES ANALYZERSep 9, 2010
167 days to decisionK100853 · Product code: **DCF** · Chemistry
Source: <https://www.510kdatabase.net/k100853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Albumin, Antigen, Antiserum, Control (DCF)
Date received	Mar 26, 2010
Decision date	Sep 9, 2010
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	ANGELO PEREIRA
510(k) history	264 submissions · 263 cleared · 1999-2013

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