

K021512 COBAS INTEGRA ONLINE DAT II METHADONE IIJul 16, 2002
68 days to decisionK021512 · Product code: **DJR** · Toxicology
Source: <https://www.510kdatabase.net/k021512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	May 9, 2002
Decision date	Jul 16, 2002
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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