

**K032453 ROCHE COMBITROL AND AUTOTROL PLUS B MULTI
ANALYTE CONTROL**Aug 28, 2003
17 days to decisionK032453 · Product code: JJY · Chemistry
Source: <https://www.510kdatabase.net/k032453/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Aug 11, 2003
Decision date	Aug 28, 2003
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionostics, Inc.
Location	Mchenry, IL, US
Contact	KATHLEEN STORRO
510(k) history	49 submissions · 49 cleared · 1983-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032453/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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