

**K043460 OLYMPUS LYOPHILIZED CHEMISTRY CALIBRATORS
DR0070 AND DR0071**Jan 31, 2005
47 days to decisionK043460 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k043460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Dec 15, 2004
Decision date	Jan 31, 2005
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	BEV HARDING
510(k) history	149 submissions · 149 cleared · 1994-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043460/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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