

**K031380 OLYMPUS HBA1C REAGENT, (CATALOG NUMBER OSR6192), OLYMPUS HBA1C CALIBRATOR, (CATOLOG NUMBER ODC3032)**Nov 14, 2003  
197 days to decisionK031380 · Product code: LCP · Chemistry  
Source: <https://www.510kdatabase.net/k031380/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 1, 2003
Decision date	Nov 14, 2003
Days to decision	197 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Olympus America, Inc.</b>
Location	Lake Success, NY, US
Contact	MICHAEL CAMPBELL
510(k) history	149 submissions · 149 cleared · 1994-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031380/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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