

K060201 OLYMPUS RF LATEX CALIBRATOR, AND OLYMPUS RF LATEX REAGENT WITH MODEL(S): ODC0028, AND OSR61105.

Jun 6, 2006
131 days to decision

K060201 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k060201/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Jan 26, 2006
Decision date	Jun 6, 2006
Days to decision	131 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.net

Device record: <https://www.510kdatabase.net/k060201/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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