

**K070453 OLYMPUS D-DIMER REAGENT, MODEL OSR6X135,
OLYMPUS D-DIMER CALIBRATOR, MODEL ODR3033,
OLYMPUS D-DIMER CONTROL**Jun 11, 2007
115 days to decisionK070453 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k070453/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Feb 16, 2007
Decision date	Jun 11, 2007
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Life & Material Science Europa GmbH (Irish
Location	Irving, TX, US
Contact	STEPHANIE G SCHWARTZ
510(k) history	3 submissions · 3 cleared · 2007-2007

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