

K080435 OLYMPUS DIRECT BILIRUBIN REAGENT, MODEL OSR6X181Sep 5, 2008
199 days to decisionK080435 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k080435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Feb 19, 2008
Decision date	Sep 5, 2008
Days to decision	199 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Olympus Life Science Research Europa GmbH (Europa)
Location	Irving, TX, US
Contact	STEPHANIE G DONNELLY
510(k) history	3 submissions · 3 cleared · 2008-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080435/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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