

K130080 EASYRA CK-MB REAGENT, EASYRA CRP REAGENT, EASY CAL CRP CALIBRATOR KIT, EASYQC CRP QUALITY CONTROL MATERIAL

May 13, 2014
484 days to decision

K130080 · Product code: **JHY** · Chemistry
Source: <https://www.510kdatabase.net/k130080/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Jan 14, 2013
Decision date	May 13, 2014
Days to decision	484 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medica Corporation
Location	Bedford, MA, US
Contact	Photios Makris
510(k) history	7 submissions · 7 cleared · 2011-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k130080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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