

K150132 IMMULITE IGF Control Module, IMMULITE Gastrin Control Module

Apr 13, 2015
82 days to decision

K150132 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k150132/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jan 21, 2015
Decision date	Apr 13, 2015
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	Asha Gartland
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k150132/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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