

K161297 Beta-2-MicroglobulinJun 7, 2016
29 days to decisionK161297 · Product code: **JZG** · Immunology
Source: <https://www.510kdatabase.net/k161297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Beta-2-microglobulin Immunological (JZG)
Date received	May 9, 2016
Decision date	Jun 7, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter Ireland, Inc.
Location	Brea, CA, US
Contact	Eimear Carr
510(k) history	7 submissions · 7 cleared · 2013-2019

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