

K161508 CeruloplasminJan 9, 2017
222 days to decisionK161508 · Product code: **DDB** · Immunology
Source: <https://www.510kdatabase.net/k161508/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ceruloplasmin, Antigen, Antiserum, Control (DDB)
Date received	Jun 1, 2016
Decision date	Jan 9, 2017
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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