

K101529 BD DIRECTIGEN EZ FLU A+B ASSAYJun 14, 2010
12 days to decisionK101529 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k101529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Jun 2, 2010
Decision date	Jun 14, 2010
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton, Dickinson & CO
Location	Franklin Lakes, NJ, US
Contact	Gregory P Payne
510(k) history	190 submissions · 190 cleared · 2001-2016

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