

K101514 BD DIRECTIGEN EZ RSVJul 9, 2010
37 days to decisionK101514 · Product code: **GQG** · Microbiology
Source: <https://www.510kdatabase.net/k101514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Controls), Respiratory Syncytial Virus (GQG)
Date received	Jun 2, 2010
Decision date	Jul 9, 2010
Days to decision	37 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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