

K101461 BD DIRECTIGEN EX FLU A+BJun 24, 2010
29 days to decisionK101461 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k101461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	May 26, 2010
Decision date	Jun 24, 2010
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton, Dickinson and Company
Location	Franklin Lakes, NJ, US
Contact	GREGORY PAYNE
Website	https://www.bd.com
510(k) history	134 submissions · 134 cleared · 2010-2026

Becton, Dickinson and Company is an American multinational medical technology company headquartered in Franklin Lakes, New Jersey. BD manufactures and sells medical devices, instrument systems, and reagents globally. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions spanning 2010 to 2026. BD's cleared devices span multiple categories including microbiology systems, blood collection products, and general hospital devices. The company's latest clearance in 2026 reflects continued innovation and regulatory engagement...

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