

**K001364 BD DIRECTIGEN FLU A+B**Jun 28, 2000  
58 days to decisionK001364 · Product code: **PSZ** · Microbiology  
Source: <https://www.510kdatabase.net/k001364/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	May 1, 2000
Decision date	Jun 28, 2000
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bd Becton Dickinson Vacutainer Systems Preanalytic</b>
Location	Washington, DC, US
Contact	Monica Giguere
510(k) history	632 submissions · 625 cleared · 1976-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001364/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 21, 2026