

K083746 BIOSIGN FLU A+BNov 10, 2010
693 days to decisionK083746 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k083746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Dec 17, 2008
Decision date	Nov 10, 2010
Days to decision	693 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Princeton BioMeditech Corp.
Location	Monmouth Junction, NJ, US
Contact	KYUNG-AH KIM
510(k) history	72 submissions · 72 cleared · 1994-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083746/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026