

K132465 BIOSIGN FLU A + B, STATUS FLU A & BSep 9, 2013
33 days to decisionK132465 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k132465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Aug 7, 2013
Decision date	Sep 9, 2013
Days to decision	33 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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