

K011684 INFLUENZA A/B RAPID TEST, CAT NO 2158 663Nov 30, 2001
184 days to decisionK011684 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k011684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	May 30, 2001
Decision date	Nov 30, 2001
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	LUANN OCHS
510(k) history	264 submissions · 263 cleared · 1999-2013

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