

K103610 CLEARVIEW EXACT II INFLUENZA A & B TEST

Jan 6, 2011
28 days to decision

K103610 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k103610/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Dec 9, 2010
Decision date	Jan 6, 2011
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alere Scarborough, Inc D/B/A Binax, Inc.
Location	Scarborough, ME, US
Contact	Anne Jepson
510(k) history	4 submissions · 4 cleared · 2011-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k103610/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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