

K092978 IMMUNOCAP RAPID READER, MODEL 12-3600-10Jan 19, 2010
113 days to decisionK092978 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k092978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Sep 28, 2009
Decision date	Jan 19, 2010
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Phadia US, Inc.
Location	Portae, MI, US
Contact	MARTIN MANN
510(k) history	22 submissions · 21 cleared · 2006-2015

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