

K071265 SMARTCHECK INR SYSTEMNov 30, 2007
207 days to decisionK071265 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k071265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	May 7, 2007
Decision date	Nov 30, 2007
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Inverness Medical Innovations, Inc.
Location	Waltham, MA, US
Contact	LESLEY MOORE
510(k) history	6 submissions · 6 cleared · 2001-2007

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