

K182793 AP3600 Automated InstrumentMar 19, 2019
169 days to decisionK182793 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k182793/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Oct 1, 2018
Decision date	Mar 19, 2019
Days to decision	169 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hitachi Chemical Diagnostics, Inc.
Location	Mountain View, CA, US
Contact	Donald Postel
510(k) history	16 submissions · 16 cleared · 2003-2021

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