

K120889 AESKUSLIDES ANA HEP-2Oct 15, 2012
206 days to decisionK120889 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k120889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	Mar 23, 2012
Decision date	Oct 15, 2012
Days to decision	206 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Aesku Diagnostics
Location	Miami, FL, US
Contact	HELENE PAXTON
510(k) history	9 submissions · 9 cleared · 2004-2013

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