

K081104 AESKULISA ANA HEP-2, REF 30-7115USMay 2, 2008
14 days to decisionK081104 · Product code: **LKJ** · Immunology
Source: <https://www.510kdatabase.net/k081104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Apr 18, 2008
Decision date	May 2, 2008
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

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

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