

K040953 AESKULISA ANA HEP-2Jun 23, 2004
72 days to decisionK040953 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k040953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Apr 12, 2004
Decision date	Jun 23, 2004
Days to decision	72 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Aesku, Inc.
Location	Miami, FL, US
Contact	STANLEY AMMONS
510(k) history	6 submissions · 6 cleared · 2003-2006

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