

K081251 MODIFICATION TO AESKULISA DS DNA GMay 13, 2008
11 days to decisionK081251 · Product code: **LSW** · Immunology
Source: <https://www.510kdatabase.net/k081251/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Anti-dna Antibody, Antigen And Control (LSW)
Date received	May 2, 2008
Decision date	May 13, 2008
Days to decision	11 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

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

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