

K132082 AESKULISA DGP-A, AESKULISA DGP-G, AESKULISA DGP-CHECK

Dec 5, 2013
153 days to decision

K132082 · Product code: **MST** · Immunology
Source: <https://www.510kdatabase.net/k132082/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Jul 5, 2013
Decision date	Dec 5, 2013
Days to decision	153 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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