

K091860 AESKULISA MPO, MODEL 30-7303USFeb 23, 2010
249 days to decisionK091860 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k091860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jun 19, 2009
Decision date	Feb 23, 2010
Days to decision	249 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.netDevice record: <https://www.510kdatabase.net/k091860/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 7, 2026