

K172461 AESKUSLIDES ANCA Ethanol, AESKUSLIDES ANCA FormalinMar 23, 2018
221 days to decisionK172461 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k172461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Aug 14, 2017
Decision date	Mar 23, 2018
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aesku.Diagnostics GmbH & Co. KG
Location	Wendelsheim, DE
Contact	Sandra Reuter
510(k) history	2 submissions · 2 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172461/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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