FDA 510(k) Premarket Notification

K091860 AESKULISA MPO, MODEL 30-7303US

CLEARED

Feb 23, 2010
249 days to decision

K091860 · 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