FDA 510(k) Premarket Notification

K132631 EIA SMDP IMMUNOASSAY

CLEARED

Aug 29, 2014
372 days to decision

K132631 · Product code: **LKP** · Immunology
Source: https://www.510kdatabase.net/k132631/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Aug 22, 2013
Decision date	Aug 29, 2014
Days to decision	372 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Phadia US, Inc.**
Location	Portae, MI, US
Contact	MARTIN ROBERT MANN
510(k) history	22 submissions · 21 cleared · 2006-2015