FDA 510(k) Premarket Notification

CLEARED

K082759 ELIA CENP IMMUNOASSAY, ELIA U1RNP IMMUNOASSAY, ELIA SM IMMUNOASSAY, ELIA RO IMMUNOASSAY

Apr 10, 2009
200 days to decision

K082759 · Product code: **LKJ** · Immunology
Source: https://www.510kdatabase.net/k082759/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Sep 22, 2008
Decision date	Apr 10, 2009
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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