FDA 510(k) Premarket Notification

K141208 DYNAMIC NEUROSCREENING DEVICE

CLEARED

Jul 23, 2014
75 days to decision

K141208 · Product code: **LQW** · Neurology
Source: https://www.510kdatabase.net/k141208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Temperature Discrimination (LQW)
Date received	May 9, 2014
Decision date	Jul 23, 2014
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Prosenex**
Location	Leola, PA, US
Contact	WILLIAM G MCLAIN
510(k) history	1 submissions · 1 cleared · 2014-2014