FDA 510(k) Premarket Notification

K101763 DIOPSYS NOVA VEP VISION TESTING SYSTEM

CLEARED

May 9, 2011
320 days to decision

K101763 · Product code: **GWE** · Neurology
Source: https://www.510kdatabase.net/k101763/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	Jun 23, 2010
Decision date	May 9, 2011
Days to decision	320 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Diopsys, Inc.**
Location	Pine Brook, NJ, US
Contact	RICHARD HETTENBACH
510(k) history	2 submissions · 2 cleared · 2005-2011