FDA 510(k) Premarket Notification

K140086 PERSONAL KINETIGRAPH (PKG) SYSTEM

CLEARED

Aug 22, 2014
220 days to decision

K140086 · Product code: **GYD** · Neurology
Source: https://www.510kdatabase.net/k140086/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Tremor (GYD)
Date received	Jan 14, 2014
Decision date	Aug 22, 2014
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gkc Manufacturing Pty, Ltd.**
Location	Rockville, MD, US
Contact	MARIE SCHROEDER
510(k) history	3 submissions · 3 cleared · 2014-2022