FDA 510(k) Premarket Notification

K161717 Personal Kinetigraph (PKG) System

CLEARED

Sep 20, 2016
90 days to decision

K161717 · Product code: **GYD** · Neurology
Source: https://www.510kdatabase.net/k161717/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Tremor (GYD)
Date received	Jun 22, 2016
Decision date	Sep 20, 2016
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k161717/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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