

K211887 Personal Kinetigraph (PKG) System Gen 2 PlusMar 11, 2022
263 days to decisionK211887 · Product code: **GYD** · Neurology
Source: <https://www.510kdatabase.net/k211887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Tremor (GYD)
Date received	Jun 21, 2021
Decision date	Mar 11, 2022
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	DuVal & Associates, P.A.
Contact	Kathy Herzog

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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