

K083603 I-PORTAL 4D VIDEO OCULOGRAPHY EYE TRACKING SYSTEM (VOG), I-PORTAL VIDEO NYSTAGMOGRAPHY SYSTEM (VNG), I-PORTAL NEURO OTOL

Aug 6, 2009
244 days to decision

K083603 · Product code: **GWN** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k083603/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Dec 5, 2008
Decision date	Aug 6, 2009
Days to decision	244 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Neuro Kinetics
Location	Pittsburgh, PA, US
Contact	Aura Kullmann
510(k) history	1 submissions · 1 cleared · 2009-2009

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k083603/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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