

K182214 DizzyDoctor System 1.0.0Sep 14, 2018
30 days to decisionK182214 · Product code: **GWN** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k182214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Aug 15, 2018
Decision date	Sep 14, 2018
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dizzydoctor Systems, LLC
Location	San Diego, CA, US
Contact	Ian Purcell
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Mark Job

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182214/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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