FDA 510(k) Premarket Notification

K182214 DizzyDoctor System 1.0.0

CLEARED

Sep 14, 2018
30 days to decision

K182214 · 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