

K163270 ISEN-Goggles with Data ViewerSep 25, 2017
308 days to decisionK163270 · Product code: **GWN** · Neurology
Source: <https://www.510kdatabase.net/k163270/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nystagmograph (GWN)
Date received	Nov 21, 2016
Decision date	Sep 25, 2017
Days to decision	308 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Isent Tech & Trading Company, Ltd.
Location	Beijing, CN
Contact	MARTIN LIU
510(k) history	1 submissions · 1 cleared · 2017-2017

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