

K171397 Sienna Ultimate Wireless AmplifierOct 6, 2017
148 days to decisionK171397 · Product code: **GWL** · Neurology
Source: <https://www.510kdatabase.net/k171397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplifier, Physiological Signal (GWL)
Date received	May 11, 2017
Decision date	Oct 6, 2017
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ems Handels Gesellschaft M.B.H.
Location	Korneuburg, AT
Contact	Ruzena Ortnerova
510(k) history	1 submissions · 1 cleared · 2017-2017

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