

**K230358 SAVI Dual (TM) Migraine Therapy**May 16, 2023  
95 days to decisionK230358 · Product code: **OKP** · Neurology  
Source: <https://www.510kdatabase.net/k230358/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transcranial Magnetic Stimulator For The Treatment Of Migraine Headache (OKP)
Date received	Feb 10, 2023
Decision date	May 16, 2023
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eneura, Inc.</b>
Location	Sunnyvale, CA, US
Contact	David Rosen
510(k) history	4 submissions · 4 cleared · 2016-2023

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