

**K200636 AXUS ES-5 Electro-Acupuncture Device**Feb 3, 2021  
330 days to decisionK200636 · Product code: **BWK** · Neurology  
Source: <https://www.510kdatabase.net/k200636/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electro-acupuncture (BWK)
Date received	Mar 10, 2020
Decision date	Feb 3, 2021
Days to decision	330 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lhasa Oms, Inc.</b>
Location	Weymouth, MA, US
Contact	Colleen Pike
510(k) history	8 submissions · 8 cleared · 2005-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ken Block Consulting, LLC</b>
Contact	Saori Sawaki

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

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