

**K230856 BrainSpec Core™ Software**Nov 14, 2023  
230 days to decisionK230856 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k230856/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 29, 2023
Decision date	Nov 14, 2023
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brainspec, Inc.</b>
Location	Boston, MA, US
Contact	Alexandra Zimmerman
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Helix Medical, LLC</b>
Contact	Carolyn Guthrie

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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