FDA 510(k) Premarket Notification

K230856 BrainSpec Core™ Software

CLEARED

Nov 14, 2023
230 days to decision

K230856 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k230856/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Helix Medical, LLC**
Contact	Carolyn Guthrie

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