FDA 510(k) Premarket Notification

CLEARED

K251009 Cirrus Resting State fMRI Software

Jun 6, 2025
66 days to decision

K251009 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k251009/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 1, 2025
Decision date	Jun 6, 2025
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sora Neuroscience, Inc.**
Location	Minneapolis, MN, US
Contact	Stephen Schaefer
Website	https://soraneuroscience.com/
510(k) history	1 submissions · 1 cleared · 2025-2025

Sora Neuroscience, Inc. develops resting-state fMRI software for brain mapping and surgical planning. The company is based in Minneapolis, Minnesota, with a team of neuroradiologists, neurosurgeons, data scientists, and software developers. Their technology builds on a decade of clinical research from Washington University in St. Louis. Sora Neuroscience has received FDA 510(k) clearance from total submission in the Radiology category. The company achieved its first and latest clearance in 2025, demonstrating active regulatory engagement. The cleared device, Cirrus Restin...

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John Smith

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