

**K231209 Rejoyn**Mar 30, 2024  
338 days to decisionK231209 · Product code: **SAP** · Neurology  
Source: <https://www.510kdatabase.net/k231209/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computerized Behavioral Therapy Device For Depressive Disorders. (SAP)
Date received	Apr 27, 2023
Decision date	Mar 30, 2024
Days to decision	338 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Otsuka America Pharmaceutical, Inc.</b>
Location	Rockville, MD, US
Contact	Nancy Teague
510(k) history	3 submissions · 3 cleared · 2023-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231209/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026