

K251088 Otsuka Digital Feedback DeviceJun 30, 2025
82 days to decisionK251088 · Product code: **OZW** · CardiovascularSource: <https://www.510kdatabase.net/k251088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ingestible Event Marker (OZW)
Date received	Apr 9, 2025
Decision date	Jun 30, 2025
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Otsuka Product Development & Commercialization, Inc.
Contact	Nancy Teague

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251088/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026