FDA 510(k) Premarket Notification

K251088 Otsuka Digital Feedback Device

CLEARED

Jun 30, 2025
82 days to decision

K251088 · Product code: **OZW** · Cardiovascular
Source: 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