

**K223463 Otsuka Digital Feedback Device-RW**Aug 11, 2023  
268 days to decisionK223463 · Product code: **OZW** · CardiovascularSource: <https://www.510kdatabase.net/k223463/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Ingestible Event Marker (OZW)      |
| Date received         | Nov 16, 2022                       |
| Decision date         | Aug 11, 2023                       |
| Days to decision      | 268 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223463/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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