

K183052 ID-Cap SystemDec 6, 2019
399 days to decisionK183052 · Product code: **OZW** · Cardiovascular
Source: <https://www.510kdatabase.net/k183052/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ingestible Event Marker (OZW)
Date received	Nov 2, 2018
Decision date	Dec 6, 2019
Days to decision	399 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Etectrx, Inc.
Location	Gainesville, FL, US
Contact	Susan Baumgartner
510(k) history	1 submissions · 1 cleared · 2019-2019

CLINICAL EVIDENCE - NCT02344238**Smart Capsule for Automatic Adherence Monitoring**

Status	Completed
Enrollment	60 patients (actual)
Study sites	1 site
Condition studied	Medication Adherence
Primary purpose	Other
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jun 1, 2016
Sponsor	Medical University of South Carolina (Other)

Primary outcome

Medication Adherence

Secondary outcome**Number of Participants Reporting Adverse Events**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02344238510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183052/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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