FDA 510(k) Premarket Notification

K150494 Proteus Digital Health Feedback Device

CLEARED

Jun 27, 2015
122 days to decision

K150494 · Product code: **OZW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k150494/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ingestible Event Marker (OZW)
Date received	Feb 25, 2015
Decision date	Jun 27, 2015
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Proteus Digital Health, Inc.**
Location	Redwood City, CA, US
Contact	Jessie Duong
510(k) history	4 submissions · 4 cleared · 2013-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k150494/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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