

**K131009 PROTEUS PATCH, INGESTIBLE SENSOR
(ACCESSORY)**May 7, 2013
26 days to decisionK131009 · Product code: **OZW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k131009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ingestible Event Marker (OZW)
Date received	Apr 11, 2013
Decision date	May 7, 2013
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131009/>; 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 June 4, 2026