

**K120489 TISSUE OF ORIGIN TEST KIT FFPE**May 17, 2012  
90 days to decisionK120489 · Product code: **OIW** · Pathology  
Source: <https://www.510kdatabase.net/k120489/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Software, Similarity Score Algorithm, Tissue Of Origin For Malignant Tumor Types (OIW)
Date received	Feb 17, 2012
Decision date	May 17, 2012
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Pathwork Diagnostics, Inc.</b>
Location	Sunnyvale, CA, US
Contact	ANNA LONGWELL
510(k) history	2 submissions · 1 cleared · 2008-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120489/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026