

K150588 OVA1 Next GenerationMar 18, 2016
375 days to decisionK150588 · Product code: **ONX** · Immunology
Source: <https://www.510kdatabase.net/k150588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ovarian Adnexal Mass Assessment Score Test System (ONX)
Date received	Mar 9, 2015
Decision date	Mar 18, 2016
Days to decision	375 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vermillion, Inc.
Location	Austin, TX, US
Contact	Benjamin A Kimball
Website	http://www.vermillion.com/
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150588/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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