

**K190661 Omics Core**Nov 9, 2019  
240 days to decisionK190661 · Product code: **PZM** · Pathology  
Source: <https://www.510kdatabase.net/k190661/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Next Generation Sequencing Based Tumor Profiling Test (PZM)
Date received	Mar 14, 2019
Decision date	Nov 9, 2019
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nanthealth, Inc.</b>
Location	Culver City, CA, US
Contact	Aleece Nolasco
510(k) history	1 submissions · 1 cleared · 2019-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190661/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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