

**K190729 SPY Portable Handheld Imaging (SPY-PHI) System**Apr 19, 2019  
29 days to decisionK190729 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190729/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SD
Submission type	Special
Device classification	Confocal Optical Imaging (OWN)
Date received	Mar 21, 2019
Decision date	Apr 19, 2019
Days to decision	29 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novadaq Technologies Ulc. (Now A Part of Stryker)</b>
Location	Burnaby, CA
Contact	Agatha Szeliga
510(k) history	6 submissions · 5 cleared · 2018-2020

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190729/> 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 June 28, 2026