

K192174 SPY Portable Handheld Imaging (SPY-PHI) SystemNov 15, 2019
95 days to decisionK192174 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Aug 12, 2019
Decision date	Nov 15, 2019
Days to decision	95 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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