

K182907 SPY Elite Intraoperative Perfusion Assessment SystemJan 23, 2019
98 days to decisionK182907 · Product code: **IZI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182907/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Oct 17, 2018
Decision date	Jan 23, 2019
Days to decision	98 days
Third-party review	No
Combination product	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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