

K190404 OTIS Optical Coherence Tomography SYstemMar 26, 2019
35 days to decisionK190404 · Product code: **NQQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Feb 19, 2019
Decision date	Mar 26, 2019
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Perimeter Medical Imaging, Inc.
Location	Toronto, CA
Contact	Elizabeth Munro
510(k) history	3 submissions · 1 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	Domecus Consulting Services, LLC
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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