

K193042 Optimized Positioning System (OPS) ReViewJun 26, 2020
239 days to decisionK193042 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k193042/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 31, 2019
Decision date	Jun 26, 2020
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Corin USA
Location	Tampa, FL, US
Contact	Lucinda Gerber
510(k) history	57 submissions · 57 cleared · 1996-2021

REGULATORY CONSULTANT

Consulting firm	Corin (Australia)
Contact	Martina Cecconi

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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