

K190162 SmartCephOct 17, 2019
259 days to decisionK190162 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k190162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 31, 2019
Decision date	Oct 17, 2019
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ortho2, LLC
Location	Ames, IA, US
Contact	Amy Schmidt
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	W. Edward Johansen
Contact	Ed Johansen

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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