FDA 510(k) Premarket Notification

K190162 SmartCeph

CLEARED

Oct 17, 2019
259 days to decision

K190162 · 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