FDA 510(k) Premarket Notification

K171617 OKI Surgical Planning Software

CLEARED

Aug 22, 2017
82 days to decision

K171617 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k171617/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 1, 2017
Decision date	Aug 22, 2017
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ortho Kinematics, Inc.**
Location	Washington, DC, US
Contact	Adam Deitz
510(k) history	6 submissions · 6 cleared · 2011-2017