FDA 510(k) Premarket Notification

K192279 PhantomMSK Trauma

CLEARED

Dec 7, 2019
107 days to decision

K192279 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k192279/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 22, 2019
Decision date	Dec 7, 2019
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**OrthoGrid Systems, Inc.**
Location	Salt Lake City, UT, US
Contact	Sebastian Edin
510(k) history	3 submissions · 3 cleared · 2019-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k192279/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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