FDA 510(k) Premarket Notification

K202519 OrthoNext Platform System

CLEARED

Oct 27, 2020
56 days to decision

K202519 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k202519/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 1, 2020
Decision date	Oct 27, 2020
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthofix Srl**
Location	Rockville, MD, US
Contact	Gianluca Ricadona
510(k) history	36 submissions · 36 cleared · 1995-2025