FDA 510(k) Premarket Notification

K220402 VirtuOst

CLEARED

May 19, 2023
462 days to decision

K220402 · Product code: **KGI** · Radiology
Source: https://www.510kdatabase.net/k220402/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Feb 11, 2022
Decision date	May 19, 2023
Days to decision	462 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**O.N. Diagnostics**
Location	Berkeley, CA, US
Contact	David Kopperdahl
510(k) history	2 submissions · 2 cleared · 2012-2023