FDA 510(k) Premarket Notification

K220822 3D-SHAPER

CLEARED

Dec 9, 2022
263 days to decision

K220822 · Product code: **KGI** · Radiology
Source: https://www.510kdatabase.net/k220822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Mar 21, 2022
Decision date	Dec 9, 2022
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**3D-Shaper Medical S.L**
Location	Barcelona, ES
Contact	Ludovic Humbert
510(k) history	2 submissions · 2 cleared · 2022-2025