FDA 510(k) Premarket Notification

K213760 ABMD Software

CLEARED

Jul 29, 2022
240 days to decision

K213760 · Product code: **KGI** · Radiology
Source: https://www.510kdatabase.net/k213760/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Dec 1, 2021
Decision date	Jul 29, 2022
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**HeartLung Corporation**
Location	Torrance, CA, US
Contact	Morteza Naghavi
510(k) history	3 submissions · 3 cleared · 2022-2025