FDA 510(k) Premarket Notification

K211443 AIBOLIT 3D+

CLEARED

Jan 7, 2022
242 days to decision

K211443 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k211443/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 10, 2021
Decision date	Jan 7, 2022
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aibolit Technologies, LLC**
Location	Delray Beach, FL, US
Contact	Howard Schrayer
510(k) history	2 submissions · 2 cleared · 2022-2023