FDA 510(k) Premarket Notification

K222458 AIBOLIT 3D+

CLEARED

Jan 12, 2023
150 days to decision

K222458 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k222458/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 15, 2022
Decision date	Jan 12, 2023
Days to decision	150 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	Gregory Piskun
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Howard Schrayer**
Contact	Howard Schrayer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov