FDA 510(k) Premarket Notification

K222577 TECHFIT Diagnostic Models

CLEARED

Jan 6, 2023
134 days to decision

K222577 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k222577/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 25, 2022
Decision date	Jan 6, 2023
Days to decision	134 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Techfit Digital Surgery, Inc.**
Location	Daytona Beach, FL, US
Contact	David Garcia-Patino
510(k) history	4 submissions · 4 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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