FDA 510(k) Premarket Notification

CLEARED

K221949 Ortho Device, ADAPTIX 3D Orthopedic Imaging System

Jan 26, 2023
205 days to decision

K221949 · Product code: **IZF** · Radiology
Source: https://www.510kdatabase.net/k221949/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	Jul 5, 2022
Decision date	Jan 26, 2023
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pausch Medical GmbH**
Location	Erlangen, DE
Contact	Christian Stoian
510(k) history	3 submissions · 3 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Oliver Eikenberg

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