

**K221949 Ortho Device, ADAPTIX 3D Orthopedic Imaging System**Jan 26, 2023  
205 days to decisionK221949 · 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	<b>Pausch Medical GmbH</b>
Location	Erlangen, DE
Contact	Christian Stoian
510(k) history	3 submissions · 3 cleared · 2016-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Emergo Global Consulting, LLC</b>
Contact	Oliver Eikenberg

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

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221949/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026