

**K243333 rTOP**Feb 4, 2025  
103 days to decisionK243333 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k243333/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 24, 2024
Decision date	Feb 4, 2025
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Roclub GmbH</b>
Location	Berlin, DE
Contact	Mario Schrenk
510(k) history	1 submissions · 1 cleared · 2025-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243333/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026