

K230119 3D Anatomic ModelMay 2, 2023
105 days to decisionK230119 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k230119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 17, 2023
Decision date	May 2, 2023
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ricoh USA, Inc.
Location	Parma, OH, US
Contact	Gary Turner
510(k) history	2 submissions · 2 cleared · 2022-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230119/> 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 27, 2026