

K223646 IB Lab LAMAJun 16, 2023
192 days to decisionK223646 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k223646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 6, 2022
Decision date	Jun 16, 2023
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ib Lab GmbH
Location	Vienna, AT
Contact	Richard Ljuhar
510(k) history	2 submissions · 2 cleared · 2019-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223646/> 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