

K201411 Visage Breast DensityJan 29, 2021
246 days to decisionK201411 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k201411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 28, 2020
Decision date	Jan 29, 2021
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Visage Imaging GmbH
Location	Berlin, DE
Contact	Stefan Strowich
510(k) history	2 submissions · 2 cleared · 2015-2021

REGULATORY CONSULTANT

Consulting firm	Qip GmbH
Contact	Juliane Dinter

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.netDevice record: <https://www.510kdatabase.net/k201411/> 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