

K231955 aprevo® Digital SegmentationNov 3, 2023
123 days to decisionK231955 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k231955/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 3, 2023
Decision date	Nov 3, 2023
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carlsmed, Inc.
Location	La Jolla, CA, US
Contact	Karen Liu
510(k) history	20 submissions · 20 cleared · 2020-2026

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