

K222676 Ceevra Reveal 3Apr 25, 2023
231 days to decisionK222676 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k222676/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 6, 2022
Decision date	Apr 25, 2023
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ceevra, Inc.
Location	Lafayette, CA, US
Contact	Ken Koster
510(k) history	5 submissions · 5 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222676/> 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 26, 2026