

**K250755 DS Core Diagnosis**Aug 12, 2025  
153 days to decisionK250755 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k250755/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 12, 2025
Decision date	Aug 12, 2025
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Dentsply Sirona, Inc.</b>
Location	York, PA, US
Contact	Deepthi Paknikar
Website	<a href="http://www.dentsply.com">http://www.dentsply.com</a>
510(k) history	21 submissions · 21 cleared · 2019-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250755/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026