

K260161 SmartGuide Disposable Guides and Grids

Jul 30, 2026
191 days to decision

K260161 · Product code: ITX · Radiology
Source: <https://www.510kdatabase.net/k260161/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jan 20, 2026
Decision date	Jul 30, 2026
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	UC-CARE , Ltd.
Location	Washington, DC, US
Contact	Hadas Sheynise
510(k) history	6 submissions · 6 cleared · 2009-2026