

K252718 Lunar AstraApr 20, 2026
235 days to decisionK252718 · Product code: **KGI** · Radiology
Source: <https://www.510kdatabase.net/k252718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Aug 28, 2025
Decision date	Apr 20, 2026
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
Location	Wauwatosa, WI, US
Contact	Christopher Paulik
510(k) history	14 submissions · 14 cleared · 2016-2026

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