

K243218 TBS iNsight (V4)Jan 17, 2025
105 days to decisionK243218 · Product code: **KGI** · Radiology
Source: <https://www.510kdatabase.net/k243218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Oct 4, 2024
Decision date	Jan 17, 2025
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medimaps Group SA
Location	Plan Les Ouates, CH
Contact	Giorgio Zoia
510(k) history	3 submissions · 3 cleared · 2012-2025

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