

K152299 TBS iNsightApr 29, 2016
260 days to decisionK152299 · Product code: **KGI** · Radiology
Source: <https://www.510kdatabase.net/k152299/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Densitometer, Bone (KGI) |
| Date received | Aug 13, 2015 |
| Decision date | Apr 29, 2016 |
| Days to decision | 260 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152299/> 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 27, 2026