

K113356 HOLOGIC VISCERAL FAT SOFTWAREMar 6, 2012
113 days to decisionK113356 · Product code: **KGI** · Radiology
Source: <https://www.510kdatabase.net/k113356/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Densitometer, Bone (KGI) |
| Date received | Nov 14, 2011 |
| Decision date | Mar 6, 2012 |
| Days to decision | 113 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Hologic, Inc. |
| Location | Waltham, MA, US |
| Contact | EILEEN M BOYLE |
| Website | https://www.hologic.com/ |
| 510(k) history | 115 submissions · 111 cleared · 1987-2025 |

Hologic, Inc. is a medical device company headquartered in Waltham, Massachusetts. The company specializes in women's health, diagnostics, and medical imaging technologies. Hologic has maintained a strong FDA 510(k) regulatory record since its founding in 1987. The company has received FDA 510(k) clearances from total submissions. Recent cleared devices span microbiology, radiology, and obstetrics & gynecology categories. The latest clearance in 2025 demonstrates continued active development and regulatory engagement. Hologic's cleared device portfolio includes molecular ...
