FDA 510(k) Premarket Notification

# K123873 CONTRAST ENHANCED DIGITAL MAMMOGRAPHY

**CLEARED**

Jan 29, 2013
43 days to decision

K123873 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k123873/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Full Field Digital, System, X-ray, Mammographic (MUE) |
| Date received | Dec 17, 2012 |
| Decision date | Jan 29, 2013 |
| Days to decision | 43 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Hologic, Inc.** |
| Location | Waltham, MA, US |
| Contact | DEBORAH THOMAS |
| 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 ...