

K091378 MAMMOSITE II RADIATION THERAPY SYSTEMJul 2, 2009
52 days to decisionK091378 · Product code: **JAQ** · Radiology
Source: <https://www.510kdatabase.net/k091378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	May 11, 2009
Decision date	Jul 2, 2009
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hologic, Inc.
Location	Waltham, MA, US
Contact	JENNIFER SULLIVAN
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 ...
