

K161575 Affirm Lateral Arm Upright Biopsy AccessoryAug 10, 2016
64 days to decisionK161575 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k161575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Jun 7, 2016
Decision date	Aug 10, 2016
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hologic
Location	Danbury, CT, US
Contact	DEBBIE PEACOCK
Website	http://www.hologic.com
510(k) history	2 submissions · 2 cleared · 2016-2025

Hologic develops innovative medical technologies for women's health, diagnostics, and medical imaging. The company operates globally across 36 countries with approximately 7,000 employees and holds over 4,100 patents. Hologic maintains a manufacturing facility in Danbury, Connecticut. The company has received FDA 510(k) clearances from total submissions since 2016. Recent cleared devices span microbiology and radiology specialties, including molecular diagnostics and imaging accessories. The latest clearance in 2025 confirms active regulatory engagement. Hologic's product...
