FDA 510(k) Premarket Notification

CLEARED

K262792 Brevera Biopsy System with CorLumina Imaging Technology (BREVDISP09)

Aug 12, 2026
6 days to decision

K262792 · Product code: **KNW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k262792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Aug 6, 2026
Decision date	Aug 12, 2026
Days to decision	6 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hologic, Inc.**
Location	Waltham, MA, US
Contact	Christine Stahley
Website	https://www.hologic.com/
510(k) history	117 submissions · 113 cleared · 1987-2026

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 ...