FDA 510(k) Premarket Notification

K253634 CoolSeal Generator® (CSL-200-90)

CLEARED

Jun 17, 2026
210 days to decision

K253634 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253634/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 19, 2025
Decision date	Jun 17, 2026
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hologic, Inc.**
Location	Waltham, MA, US
Contact	Brynn Dietzel
Website	https://www.hologic.com/
510(k) history	116 submissions · 112 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 ...