FDA 510(k) Premarket Notification

K252183 Resitu Slider 09 (RESL09)

CLEARED

Sep 24, 2025
75 days to decision

K252183 · Product code: **KNW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k252183/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 11, 2025
Decision date	Sep 24, 2025
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Resitu Medical AB**
Location	Uppsala, SE
Contact	Asa Runnas
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov