FDA 510(k) Premarket Notification

K251989 VizMark Preloaded Tissue Marker Device (VM-0001)

CLEARED

Dec 12, 2025
168 days to decision

K251989 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k251989/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Jun 27, 2025
Decision date	Dec 12, 2025
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Breast-Med, Inc.**
Location	Golden Valley, MN, US
Contact	Michael Nelson
510(k) history	2 submissions · 2 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	**Carbon Medical Technologies, Inc.**
Contact	Yidi Hou

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