

K241762 OneMarkSep 16, 2024
88 days to decisionK241762 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241762/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Jun 20, 2024
Decision date	Sep 16, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	View Point Medical
Location	Carlsbad, CA, US
Contact	Tom Kane
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Randy Prebula

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

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