FDA 510(k) Premarket Notification

K241762 OneMark

CLEARED

Sep 16, 2024
88 days to decision

K241762 · Product code: **NEU** · General & Plastic Surgery
Source: 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