

K190689 SignalMark Breast MarkerAug 14, 2019
149 days to decisionK190689 · Product code: **NEU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k190689/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Mar 18, 2019
Decision date	Aug 14, 2019
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	View Point Medical, Inc.
Location	San Clemente, CA, US
Contact	Thomas Kane
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Michelle Rubin-Onur

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

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