FDA 510(k) Premarket Notification

K210600 MOLLI

CLEARED

Apr 16, 2021
46 days to decision

K210600 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k210600/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Mar 1, 2021
Decision date	Apr 16, 2021
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Molli Surgical, Inc.**
Location	Toronto, CA
Contact	Fazila Seker
510(k) history	5 submissions · 5 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**Acknowlegde Regulatory Strategies, LLC**
Contact	Pierre Bounaud

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