FDA 510(k) Premarket Notification

K234149 MOLLI 2 System

CLEARED

Sep 26, 2024
272 days to decision

K234149 · Product code: **NEU** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k234149/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Marker, Radiographic, Implantable (NEU)
Date received	Dec 29, 2023
Decision date	Sep 26, 2024
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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