FDA 510(k) Premarket Notification

K223272 SurBlate Ablation System

CLEARED

Feb 28, 2023
127 days to decision

K223272 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223272/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Oct 24, 2022
Decision date	Feb 28, 2023
Days to decision	127 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mima-Pro Scientific, Inc.**
Location	Richmond, CA
Contact	Jim Elliott
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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