FDA 510(k) Premarket Notification

K233884 INUMI™ Flex Needle

CLEARED

May 22, 2024
166 days to decision

K233884 · Product code: **OAB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233884/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Energy Direct Current Thermal Ablation System (OAB)
Date received	Dec 8, 2023
Decision date	May 22, 2024
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Galvanize Therapeutics, Inc.**
Location	San Carlos, CA, US
Contact	Deborah Sheffield
510(k) history	2 submissions · 2 cleared · 2022-2024