FDA 510(k) Premarket Notification

K243929 Oligio X

CLEARED

Jan 21, 2025
32 days to decision

K243929 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243929/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 20, 2024
Decision date	Jan 21, 2025
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wontech Co., Ltd.**
Location	Daejeon, KR
Contact	Hyun Sik Yoon
510(k) history	28 submissions · 28 cleared · 2017-2025