FDA 510(k) Premarket Notification

K242996 EndyMed PRO MAX

CLEARED

Jun 10, 2025
257 days to decision

K242996 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242996/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 26, 2024
Decision date	Jun 10, 2025
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Endymed Medical, Ltd.**
Location	Binyamina, IL
Contact	Ohad Fisher
510(k) history	8 submissions · 7 cleared · 2011-2025