FDA 510(k) Premarket Notification

K250852 Coolfase

CLEARED

Oct 16, 2025
209 days to decision

K250852 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250852/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 21, 2025
Decision date	Oct 16, 2025
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Asterasys Co., Ltd.**
Location	Seoul, KR
Contact	Chayeon Kim
510(k) history	1 submissions · 1 cleared · 2025-2025