FDA 510(k) Premarket Notification

K220996 Duoblade

CLEARED

Feb 3, 2023
305 days to decision

K220996 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220996/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 4, 2022
Decision date	Feb 3, 2023
Days to decision	305 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cnc Technologies**
Location	Gwangmyeong-Si, KR
Contact	InSang Choi
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**KMC, Inc.**
Contact	WooSeok Jeong

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