FDA 510(k) Premarket Notification

K222709 Retraction, CWM-910T, APOLEX Tite

CLEARED

Mar 21, 2023
194 days to decision

K222709 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 8, 2022
Decision date	Mar 21, 2023
Days to decision	194 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Chungwoo Co., Ltd.**
Location	Seoul, KR
Contact	Il Kwon Lee
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**KMC, Inc.**
Contact	Milly ,

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