FDA 510(k) Premarket Notification

K203013 AGNES

CLEARED

Jul 14, 2022
651 days to decision

K203013 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 1, 2020
Decision date	Jul 14, 2022
Days to decision	651 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Agnes Medical Co., Ltd.**
Location	Seongnam-Si, KR
Contact	Chul Lee
510(k) history	7 submissions · 7 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	**KMC, Inc.**
Contact	DongHa Lee

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