FDA 510(k) Premarket Notification

K212472 AgeJet

CLEARED

Jul 7, 2022
335 days to decision

K212472 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212472/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 6, 2021
Decision date	Jul 7, 2022
Days to decision	335 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Triworks Group Srl**
Location	Campobasso, IT
Contact	Elio Piero Berchicci
510(k) history	2 submissions · 2 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	**Neoconcepts, LLC**
Contact	Matthew Brulport

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