FDA 510(k) Premarket Notification

K230432 Single Use Bipolar Forceps

CLEARED

May 18, 2023
90 days to decision

K230432 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230432/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 17, 2023
Decision date	May 18, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hg Innovations, Ltd.**
Location	Lancashire, GB
Contact	Dr.M Umran Rafiq
510(k) history	3 submissions · 3 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Medical Device Academy, Inc.**
Contact	Wondwossen Tekolla

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