FDA 510(k) Premarket Notification

K252215 InbellaMAX System

CLEARED

Jul 25, 2025
10 days to decision

K252215 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k252215/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 15, 2025
Decision date	Jul 25, 2025
Days to decision	10 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inbella Medical , Ltd.**
Location	Richmond Hill, CA
Contact	Michael Kreindel
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Jodi K. Scott

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