

K211217 Profound MatrixDec 16, 2021
237 days to decisionK211217 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211217/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 23, 2021
Decision date	Dec 16, 2021
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Candela Corporation
Location	Wayland, MA, US
Contact	Jeffrey Churchill
510(k) history	8 submissions · 8 cleared · 2015-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211217/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026