

K250327 OptaBlate Radiofrequency (RF) Generator SystemApr 15, 2025
69 days to decisionK250327 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250327/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Feb 5, 2025 |
| Decision date | Apr 15, 2025 |
| Days to decision | 69 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Stryker Instruments |
| Location | Kalamazoo, MI, US |
| Contact | Josh Measures |
| 510(k) history | 72 submissions · 72 cleared · 1994-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250327/> 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 14, 2026