

K201212 Voyant Open Fusion DeviceJun 5, 2020
31 days to decisionK201212 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201212/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | May 5, 2020 |
| Decision date | Jun 5, 2020 |
| Days to decision | 31 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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|----------------|---|
| Company | Applied Medical Resources Corp. |
| Location | Rancho Santa, CA, US |
| Contact | Sherif Nakhla |
| 510(k) history | 45 submissions · 45 cleared · 2001-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201212/> 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