

K211206 FreedomEdge(R) Syringe Infusion SystemNov 9, 2021
201 days to decisionK211206 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k211206/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Infusion (FRN) |
| Date received | Apr 22, 2021 |
| Decision date | Nov 9, 2021 |
| Days to decision | 201 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Repro-Medical System, Inc., Db a Koru Medical Systems |
| Location | New York, NY, US |
| Contact | Brian Schiller |
| 510(k) history | 2 submissions · 2 cleared · 2021-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211206/> 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