

K251757 Puracyn® Plus Antimicrobial Irrigation SolutionJan 5, 2026
210 days to decisionK251757 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251757/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Jun 9, 2025 |
| Decision date | Jan 5, 2026 |
| Days to decision | 210 days |
| Third-party review | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Innovacyn, Inc. |
| Location | Rialto, CA, US |
| Contact | Hungnan Lo |
| 510(k) history | 4 submissions · 4 cleared · 2014-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251757/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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