

K221754 Ag Foam Dressing Non-Adhesive (OTC)Jan 17, 2023
215 days to decisionK221754 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221754/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Jun 16, 2022 |
| Decision date | Jan 17, 2023 |
| Days to decision | 215 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Ag Foam Dressing Adhesive (OTC); Silicone Ag Foam Dressing (OTC); Silicone Ag Foam Dressing with Border (OTC) |

APPLICANT

| | |
|----------------|---|
| Company | Winner Medical Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Zhiqin Liang |
| 510(k) history | 18 submissions · 18 cleared · 2019-2025 |

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