

K242839 Safe Secure Sterilization Pouches and RollsOct 16, 2024
27 days to decisionK242839 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k242839/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wrap, Sterilization (FRG) |
| Date received | Sep 19, 2024 |
| Decision date | Oct 16, 2024 |
| Days to decision | 27 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Shenzhen Safesecure Medical Infection Control Tech Co. , Ltd. |
| Location | Shenzhen, CN |
| Contact | Parker Lee |
| 510(k) history | 3 submissions · 3 cleared · 2022-2025 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Regulatory Technology Services, LLC |
| Contact | Prithul Bom |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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