

**K112591 SAFE SECURE STERILIZATION POUCH WITH  
STEAM AND ETHYLENE OXIDE PROCESS INDICATORS**Feb 7, 2012  
153 days to decisionK112591 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k112591/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Wrap, Sterilization (FRG)          |
| Date received         | Sep 7, 2011                        |
| Decision date         | Feb 7, 2012                        |
| Days to decision      | 153 days                           |
| Third-party review    | Yes                                |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Safe Secure Packaging Co., Ltd.</b> |
| Location       | Shenzhen, Guangdong, CN                |
| Contact        | GARFIELD WANG                          |
| 510(k) history | 2 submissions · 2 cleared · 2012-2016  |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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