

**K062704 STERILIZATION POUCH WITH INDICATORS**Jun 8, 2007  
270 days to decisionK062704 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k062704/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Sep 11, 2006
Decision date	Jun 8, 2007
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Winner Industries (Shenzhen) Co., Ltd.</b>
Location	Ontario, CA, US
Contact	MING XIE
510(k) history	2 submissions · 2 cleared · 2003-2007

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062704/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026