

K023755 WINNER EAR LOOP PROCEDURE MASK, TIE-ON SURGICAL MASK & EAR LOOP PROCEDURE MASK WITH SHIELD

Jun 10, 2003
214 days to decision

K023755 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k023755/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 8, 2002
Decision date	Jun 10, 2003
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k023755/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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