

K063043 SURGICAL FACE MASK, TYPE: TIE-ON, EAR-LOOPMar 21, 2007
169 days to decisionK063043 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k063043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 3, 2006
Decision date	Mar 21, 2007
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Modern Healthcare Corp.
Location	Hsin-Chu City, TW
Contact	JEN KE-MIN
510(k) history	3 submissions · 3 cleared · 2007-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063043/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026