

**K123115 ACME SURGICAL FACE MASK WITH EAR-LOOP  
MODEL YN-501 AB/W/G/P**

May 20, 2013  
229 days to decision

K123115 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k123115/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 3, 2012
Decision date	May 20, 2013
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Acme Filter Mask, Inc.</b>
Location	New Taipei City, TW
Contact	JEN KE-MIN
510(k) history	1 submissions · 1 cleared · 2013-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k123115/> 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 8, 2026