

**K171162 Surgical Earloop Face Mask with Bottom Gap Shield
and Surgical Tie-On Face Mask with Bottom Gap Shield**Aug 15, 2017
117 days to decisionK171162 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k171162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Apr 20, 2017
Decision date	Aug 15, 2017
Days to decision	117 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Prestige Ameritech
Location	Fort Worth, TX, US
Contact	Rex Reese
510(k) history	5 submissions · 5 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171162/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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