

K112796 SURGICAL GOWN (EO STERILIZED)Sep 12, 2013
717 days to decisionK112796 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k112796/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 26, 2011
Decision date	Sep 12, 2013
Days to decision	717 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cobes Industries Co., Ltd.
Location	Dover, DE, US
Contact	LEON LU
510(k) history	3 submissions · 3 cleared · 2012-2014

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