

**K121998 HM SURGICAL GOWN, NON REINFORCED HM
SURGICAL GOWN, FABRIC REINFORCED HM SURGICAL
GOWN, POLYERINFORCED**

Dec 20, 2012
164 days to decision

K121998 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k121998/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jul 9, 2012
Decision date	Dec 20, 2012
Days to decision	164 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Changzhou Holymed Products Co., Ltd.
Location	Changhou, CN
Contact	ALAN YU
510(k) history	3 submissions · 3 cleared · 2012-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k121998/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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