

K971920 GOWN POLY REINFORCED LARGE(PRODUCT NO.900-522)/(REORDER NO. 0522)Dec 4, 1997
195 days to decisionK971920 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k971920/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	May 23, 1997
Decision date	Dec 4, 1997
Days to decision	195 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Customed, Inc.
Location	Carolina Puerto Rico, US
Contact	GLADYNELL RODRIQUEZ
510(k) history	36 submissions · 26 cleared · 1990-1998

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