

K043004 STACKHOUSE FREEDOMAIRE II SURGICAL HELMET SYSTEM, MODELS 12000, 12010, 12011, 12020, 12021, 12022, 12030, 12031Mar 16, 2005
135 days to decisionK043004 · Product code: FYA · General Hospital
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 1, 2004
Decision date	Mar 16, 2005
Days to decision	135 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Viasys Medsystems
Location	Wheeling, IL, US
Contact	STEPHANIE WASIELEWSKI
510(k) history	7 submissions · 7 cleared · 2004-2008

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