

K122702 BIOFRIEND BIOMASK N95 SURGICAL RESPIRATORMar 18, 2013
195 days to decisionK122702 · Product code: **ONT** · General Hospital
Source: <https://www.510kdatabase.net/k122702/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	N95 Respirator With Antimicrobial/antiviral Agent (ONT)
Date received	Sep 4, 2012
Decision date	Mar 18, 2013
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Filligent Limited
Location	Austin, TX, US
Contact	KAI DEUSCH
510(k) history	2 submissions · 2 cleared · 2011-2013

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