

K081923 ACTIPROTECT UF N95 RESPIRATOR, DOUBLE STRAP, FLAT FOLDJul 1, 2009
359 days to decisionK081923 · Product code: **ONT** · General Hospital
Source: <https://www.510kdatabase.net/k081923/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	N95 Respirator With Antimicrobial/antiviral Agent (ONT)
Date received	Jul 7, 2008
Decision date	Jul 1, 2009
Days to decision	359 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Glaxosmithkline Consumer Healthcare
Location	Parsippany, NJ, US
Contact	ZINATARA A MANJI
510(k) history	3 submissions · 3 cleared · 2009-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081923/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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