

K093161 ACTIPROTECT UF N95 RESPIRATORMay 10, 2010
216 days to decisionK093161 · Product code: **ONT** · General Hospital
Source: <https://www.510kdatabase.net/k093161/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | N95 Respirator With Antimicrobial/antiviral Agent (ONT) |
| Date received | Oct 6, 2009 |
| Decision date | May 10, 2010 |
| Days to decision | 216 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 |

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