

**K101128 BIOFRIEND BIOMASK SURGICAL FACEMASK,
MODELS UNIVERSAL BF-200-2001 AND PREMIUM BF-200-3013**May 26, 2011
399 days to decisionK101128 · Product code: **OUK** · General Hospital
Source: <https://www.510kdatabase.net/k101128/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Surgical Mask With Antimicrobial/antiviral Agent (OUK) |
| Date received | Apr 22, 2010 |
| Decision date | May 26, 2011 |
| Days to decision | 399 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101128/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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