

**K123731 BIOTENE ORAL BALANCE GEL, BIOTENE DRY
MOUTH ORAL RINSE, BIOTENE MOISTURIZING MOUTH SPRAY**Jan 4, 2013
30 days to decisionK123731 · Product code: LFD · Dental
Source: <https://www.510kdatabase.net/k123731/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Saliva, Artificial (LFD)
Date received	Dec 5, 2012
Decision date	Jan 4, 2013
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Glaxosmithkline Consumer Healthcare (Gskch)
Location	Parsippany, NJ, US
Contact	PAUL KRUMM
510(k) history	3 submissions · 3 cleared · 2010-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123731/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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