

**K101477 BIOTENE DRY MOUTH MOUTHWASH, BIOTENE PBF
 DRY MOUTH MOUTHWASH**

Sep 28, 2010
 123 days to decision

K101477 · Product code: LFD · Dental
 Source: <https://www.510kdatabase.net/k101477/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saliva, Artificial (LFD)
Date received	May 28, 2010
Decision date	Sep 28, 2010
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k101477/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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