FDA 510(k) Premarket Notification

K101477 BIOTENE DRY MOUTH MOUTHWASH, BIOTENE PBF DRY MOUTH MOUTHWASH

CLEARED

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