FDA 510(k) Premarket Notification

K082594 REMESENSE

CLEARED

Mar 19, 2009
192 days to decision

K082594 · Product code: **LBH** · Dental
Source: https://www.510kdatabase.net/k082594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Sep 8, 2008
Decision date	Mar 19, 2009
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Remedent NV**
Location	Lake Forest, CA, US
Contact	WILLIAM GREENROSE
510(k) history	2 submissions · 2 cleared · 2003-2009