FDA 510(k) Premarket Notification

K131430 CLEARFIL DC ACTIVATOR

CLEARED

Aug 30, 2013
105 days to decision

K131430 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k131430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	May 17, 2013
Decision date	Aug 30, 2013
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary
Other names	CLEARFIL DC ACTIVATOR TRIAL

APPLICANT

Company	**Kuraray Noritake Dental, Inc.**
Location	New York, NY, US
Contact	MICHIO TAKIGAWA
510(k) history	32 submissions · 32 cleared · 2012-2025