FDA 510(k) Premarket Notification

K134022 BASE IT

CLEARED

Jun 11, 2014
163 days to decision

K134022 · Product code: **EJK** · Dental
Source: https://www.510kdatabase.net/k134022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Liner, Cavity, Calcium Hydroxide (EJK)
Date received	Dec 30, 2013
Decision date	Jun 11, 2014
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spident Co., Ltd.**
Location	Incheon, KR
Contact	LENA PAK
510(k) history	17 submissions · 17 cleared · 2009-2025