FDA 510(k) Premarket Notification

K060347 B&L L-BETA, MODEL WL-B1

CLEARED

Jun 5, 2006
115 days to decision

K060347 · Product code: **EKR** · Dental
Source: https://www.510kdatabase.net/k060347/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plugger, Root Canal, Endodontic (EKR)
Date received	Feb 10, 2006
Decision date	Jun 5, 2006
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**B&L Biotech Co., Ltd.**
Location	Deer Field, IL, US
Contact	DANIEL KAMM
510(k) history	1 submissions · 1 cleared · 2006-2006