FDA 510(k) Premarket Notification

K080025 LED.L, LED.M, LED.G, LED.B

CLEARED

Mar 19, 2008
75 days to decision

K080025 · Product code: **EBZ** · Dental
Source: https://www.510kdatabase.net/k080025/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activator, Ultraviolet, For Polymerization (EBZ)
Date received	Jan 4, 2008
Decision date	Mar 19, 2008
Days to decision	75 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	**Guilin Woodpecker Medical Instrument Co., Ltd.**
Location	Flintville, TN, US
Contact	CHARLIE MACK
510(k) history	14 submissions · 14 cleared · 2006-2025