FDA 510(k) Premarket Notification

K092251 BIODENTINE

CLEARED

Oct 30, 2009
94 days to decision

K092251 · Product code: **KIF** · Dental
Source: https://www.510kdatabase.net/k092251/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Jul 28, 2009
Decision date	Oct 30, 2009
Days to decision	94 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Septodont**
Location	Washington, DC, US
Contact	WAYNE MATELSKI
510(k) history	9 submissions · 9 cleared · 2003-2021