FDA 510(k) Premarket Notification

K091331 PIEZOTOME 2

CLEARED

Dec 11, 2009
220 days to decision

K091331 · Product code: **DZI** · Dental
Source: https://www.510kdatabase.net/k091331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	May 5, 2009
Decision date	Dec 11, 2009
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Satelec**
Location	Merignac, FR
Contact	RICK ROSATI
510(k) history	24 submissions · 24 cleared · 1990-2011