FDA 510(k) Premarket Notification

K112188 PIEZOTOME SOLO

CLEARED

Feb 3, 2012
189 days to decision

K112188 · Product code: **DZI** · Dental
Source: https://www.510kdatabase.net/k112188/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	Jul 29, 2011
Decision date	Feb 3, 2012
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Satelec - Acteon, Inc.**
Location	Mt. Laurel, NJ, US
Contact	RICK ROSATI
510(k) history	1 submissions · 1 cleared · 2012-2012