FDA 510(k) Premarket Notification

K133488 PIEZOMED

CLEARED

Oct 16, 2014
337 days to decision

K133488 · Product code: **DZI** · Dental
Source: https://www.510kdatabase.net/k133488/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	Nov 13, 2013
Decision date	Oct 16, 2014
Days to decision	337 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**W&H Dentalwerk Buermoos GmbH**
Location	Buermoos, AT
Contact	ANJA LINDNER
510(k) history	17 submissions · 17 cleared · 1999-2025