FDA 510(k) Premarket Notification

K043408 PIEZOSURGERY DEVICE

CLEARED

Jun 8, 2005
180 days to decision

K043408 · Product code: **DZI** · Dental
Source: https://www.510kdatabase.net/k043408/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	Dec 10, 2004
Decision date	Jun 8, 2005
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Piezosurgery S.R.L.**
Location	Rome, IT
Contact	Maria E Donawa
510(k) history	4 submissions · 4 cleared · 2005-2009