FDA 510(k) Premarket Notification

K152125 Oral Surgery System and Accessories

CLEARED

Aug 15, 2016
381 days to decision

K152125 · Product code: **DZI** · Dental
Source: https://www.510kdatabase.net/k152125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	Jul 31, 2015
Decision date	Aug 15, 2016
Days to decision	381 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Bonart Co., Ltd.**
Location	Hsingchang, Taipei Hsien, TW
Contact	BANKSON TSAI
510(k) history	14 submissions · 14 cleared · 2000-2017