

**K152125 Oral Surgery System and Accessories**Aug 15, 2016  
381 days to decisionK152125 · Product code: **DZI** · Dental  
Source: <https://www.510kdatabase.net/k152125/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152125/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 1, 2026