

**K231087 Guided Surgery Kit**Aug 16, 2023  
121 days to decisionK231087 · Product code: **DZI** · General HospitalSource: <https://www.510kdatabase.net/k231087/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Bone, Powered (DZI)
Date received	Apr 17, 2023
Decision date	Aug 16, 2023
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Implant Direct Sybron Manufacturing, LLC</b>
Location	Calabasas, CA, US
Contact	Reina Choi
510(k) history	17 submissions · 17 cleared · 2013-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231087/> 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 May 13, 2026