FDA 510(k) Premarket Notification

K231087 Guided Surgery Kit

CLEARED

Aug 16, 2023
121 days to decision

K231087 · Product code: **DZI** · General Hospital
Source: https://www.510kdatabase.net/k231087/

SUBMISSION DETAILS

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

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