

**K201353 CenterMed Patient Matched Assisted Surgical Planning (ASP) System**Jun 28, 2021  
403 days to decisionK201353 · Product code: **DZJ** · Dental  
Source: <https://www.510kdatabase.net/k201353/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Driver, Wire, And Bone Drill, Manual (DZJ)
Date received	May 21, 2020
Decision date	Jun 28, 2021
Days to decision	403 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Centermed, Inc.</b>
Location	Walnut Creek, CA, US
Contact	Christine Yu
510(k) history	2 submissions · 2 cleared · 2021-2022

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Scientific Solutions R US</b>
Contact	Jash Bhayani

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201353/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026