

K193499 DigiGuide SystemNov 4, 2020
323 days to decisionK193499 · Product code: **DZJ** · Dental
Source: <https://www.510kdatabase.net/k193499/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Driver, Wire, And Bone Drill, Manual (DZJ) |
| Date received | Dec 17, 2019 |
| Decision date | Nov 4, 2020 |
| Days to decision | 323 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Protomed, Inc. |
| Location | Westminster, CO, US |
| Contact | James Jimenez |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193499/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026