FDA 510(k) Premarket Notification

CLEARED

K201353 CenterMed Patient Matched Assisted Surgical Planning (ASP) System

Jun 28, 2021
403 days to decision

K201353 · 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	**Centermed, Inc.**
Location	Walnut Creek, CA, US
Contact	Christine Yu
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**Scientific Solutions R US**
Contact	Jash Bhayani

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov