

K230398 MedCAD® AccuPlate® 3DTi Patient-Specific Plating System

Sep 26, 2023
222 days to decision

K230398 · Product code: JEY · Dental
Source: <https://www.510kdatabase.net/k230398/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Feb 16, 2023
Decision date	Sep 26, 2023
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medcad
Location	Dallas, TX, US
Contact	Brian Buss
510(k) history	9 submissions · 9 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	Secure BioMed Evaluations
Contact	Justin Gracyalny

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

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Device record: <https://www.510kdatabase.net/k230398/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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