

K193280 MedCAD® AccuPlate® Patient-Specific PlateFeb 12, 2021
443 days to decision

K193280 · Product code: JEY · Dental

Source: <https://www.510kdatabase.net/k193280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Nov 27, 2019
Decision date	Feb 12, 2021
Days to decision	443 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	Linda Braddon

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

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