FDA 510(k) Premarket Notification

CLEARED

K220357 MedCAD AccuShape Titanium Patient-Specific Cranial Implant

Aug 26, 2022
199 days to decision

K220357 · Product code: **GXN** · Neurology
Source: https://www.510kdatabase.net/k220357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Feb 8, 2022
Decision date	Aug 26, 2022
Days to decision	199 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