

**K180204 CranioMaxillofacial Fixation (CMF) System - CMF
Visionare**Dec 28, 2018
338 days to decisionK180204 · Product code: JEY · Dental
Source: <https://www.510kdatabase.net/k180204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Jan 24, 2018
Decision date	Dec 28, 2018
Days to decision	338 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Visionare, LLC
Location	Fort Myers, FL, US
Contact	Mariane de Oliveira Quinzani
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Kevin Thomas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180204/>; 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