FDA 510(k) Premarket Notification

K180204 CranioMaxillofacial Fixation (CMF) System - CMF Visionare

CLEARED

Dec 28, 2018
338 days to decision

K180204 · 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