

K191997 FAICO CMF SystemApr 22, 2020
271 days to decisionK191997 · Product code: **JEY** · Dental
Source: <https://www.510kdatabase.net/k191997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Jul 26, 2019
Decision date	Apr 22, 2020
Days to decision	271 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Faico Medical, LLC
Location	Boca Raton, FL, US
Contact	Heman Dario Fernandez
510(k) history	3 submissions · 3 cleared · 2020-2021

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