

K203282 TECHFIT Patient-Specific Maxillofacial SystemMay 19, 2021
194 days to decisionK203282 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k203282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Nov 6, 2020
Decision date	May 19, 2021
Days to decision	194 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Industrias Medicas Sampedro S.A.S
Location	La Estrella, CO
Contact	Leidy Johanna Toro Gonzalez
510(k) history	2 submissions · 2 cleared · 2019-2021

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