

K182609 Delphos Implants Rigid Fixation SystemMar 29, 2019
189 days to decisionK182609 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k182609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Sep 21, 2018
Decision date	Mar 29, 2019
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Delphos Implants - Ind.Com. Importacao E Exportacao DE
Location	Armazem. No5 Cascais, PT
Contact	Vitor Monsanto
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Passarini Regulatory Affairs of America, LLC
Contact	Mauro Malzyner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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