

K180249 OmniPore DUROMAX Surgical ImplantsOct 11, 2018
255 days to decisionK180249 · Product code: **JEY** · Dental
Source: <https://www.510kdatabase.net/k180249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Jan 29, 2018
Decision date	Oct 11, 2018
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Matrix Surgical Holdings, LLC/Matrix Surgical USA
Location	Alpharetta, GA, US
Contact	John O'Shaughnessy
510(k) history	2 submissions · 2 cleared · 2014-2018

REGULATORY CONSULTANT

Consulting firm	Regulatory Resources Group, Inc.
Contact	Julie Stephens

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

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