

K210871 PDO Max Suture with Dual NeedleDec 17, 2021
268 days to decisionK210871 · Product code: **NEW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210871/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Mar 24, 2021
Decision date	Dec 17, 2021
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pdo Max, Inc.
Location	Liverpool, NY, US
Contact	Giovanna McCarthy
510(k) history	2 submissions · 2 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Mary Vater

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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