

**K251414 Miracu™ Polydioxanone (PDO) Suture and Needle (MONO)**Oct 20, 2025  
166 days to decisionK251414 · Product code: **NEW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k251414/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	May 7, 2025
Decision date	Oct 20, 2025
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Feeltech Co., Ltd.</b>
Location	Gunsan-Si, KR
Contact	Choi Cheol-Ho
510(k) history	4 submissions · 4 cleared · 2018-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Albert Rego PHD, Inc (D.B.A Rego Associates)</b>
Contact	Albert Rego

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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