

**K190264 Viola**Aug 15, 2019  
188 days to decisionK190264 · Product code: **NEW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190264/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Feb 8, 2019
Decision date	Aug 15, 2019
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Meditime Co., Ltd.</b>
Location	Won Ju, KR
Contact	Yong Baik Kim
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bio-Med USA, Inc.</b>
Contact	Young Chi

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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