

**K241977 Injectable Root Canal Bioceramic Sealer (i-MTA SP)**Oct 3, 2024  
90 days to decisionK241977 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k241977/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Jul 5, 2024
Decision date	Oct 3, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Longly Biotechnology (Wuhan) Co., Ltd.</b>
Location	Wuhan, CN
Contact	Liang Yan
510(k) history	2 submissions · 2 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Wuhan Tacro Technology Co., Ltd.</b>
Contact	Alice Wu

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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