

K242934 Bioceramic Root Canal Sealer and Repair Materials (i-MTA BP)Dec 12, 2024
78 days to decisionK242934 · Product code: **KIF** · Dental
Source: <https://www.510kdatabase.net/k242934/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Resin, Root Canal Filling (KIF) |
| Date received | Sep 25, 2024 |
| Decision date | Dec 12, 2024 |
| Days to decision | 78 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Beijing Xinranyicheng Medicine & Technology Co., Ltd. |
| Contact | Shirely Kong |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242934/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026