

K200174 DIA-ROOT BIO MTASep 18, 2020
239 days to decisionK200174 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k200174/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Resin, Root Canal Filling (KIF) |
| Date received | Jan 23, 2020 |
| Decision date | Sep 18, 2020 |
| Days to decision | 239 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | DiaDent Group International |
| Location | Chungcheong Buk-Do, KR |
| Contact | Kab Sun Lee |
| 510(k) history | 19 submissions · 19 cleared · 2013-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200174/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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