

K242317 Integrated Endo System (Meet Endo-II)Feb 13, 2025
192 days to decisionK242317 · Product code: **ELC** · DentalSource: <https://www.510kdatabase.net/k242317/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Scaler, Ultrasonic (ELC) |
| Date received | Aug 5, 2024 |
| Decision date | Feb 13, 2025 |
| Days to decision | 192 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Denjoy Dental Co., Ltd. |
| Location | Changsha, CN |
| Contact | Chengfa Huang |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242317/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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