

K243336 Lucitone Digital Print Denture™ SystemDec 17, 2024
54 days to decisionK243336 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k243336/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Resin, Denture, Relining, Repairing, Rebasing (EBI) |
| Date received | Oct 24, 2024 |
| Decision date | Dec 17, 2024 |
| Days to decision | 54 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dentsply Sirona, Inc. |
| Location | York, PA, US |
| Contact | Melanie Avila |
| Website | http://www.dentsply.com |
| 510(k) history | 21 submissions · 21 cleared · 2019-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243336/> 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