

K964323 CHROMOPRINT CHROMATIC ALGINATE IMPRESSION MATERIALDec 16, 1996
47 days to decisionK964323 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k964323/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Material, Impression (ELW) |
| Date received | Oct 30, 1996 |
| Decision date | Dec 16, 1996 |
| Days to decision | 47 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Fen Dental Mfg., Inc. |
| Location | Miami, FL, US |
| Contact | ROBERT W BAUER, PH.D. |
| 510(k) history | 3 submissions · 3 cleared · 1994-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964323/> 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 July 3, 2026