

K853447 POLYCARB WATER SETOct 16, 1985
61 days to decisionK853447 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k853447/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cement, Dental (EMA) |
| Date received | Aug 16, 1985 |
| Decision date | Oct 16, 1985 |
| Days to decision | 61 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Puldent Corp. of America |
| Location | Mchenry, IL, US |
| Contact | KENNETH J BERK |
| 510(k) history | 6 submissions · 6 cleared · 1981-1988 |

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