

K062897 C-U2Dec 14, 2006
78 days to decisionK062897 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k062897/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Unit, Operative Dental (EIA) |
| Date received | Sep 27, 2006 |
| Decision date | Dec 14, 2006 |
| Days to decision | 78 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cefla S.C.R.L. |
| Location | Ormond Beach, FL, US |
| Contact | Claude Berthoin |
| 510(k) history | 3 submissions · 3 cleared · 2006-2008 |

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