

K032851 ULTRACROWN 75 ALLOYSep 26, 2003
14 days to decisionK032851 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k032851/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Alloy, Gold-based Noble Metal (EJT) |
| Date received | Sep 12, 2003 |
| Decision date | Sep 26, 2003 |
| Days to decision | 14 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dentsply International |
| Location | York, PA, US |
| Contact | P. JEFFERY LEHN |
| 510(k) history | 23 submissions · 23 cleared · 2001-2012 |

Dentsply International is an American dental equipment manufacturer and consumables producer headquartered in York, US. The company designs and manufactures laboratory and specialty products for dental applications, serving markets in over 120 countries. Dentsply International has received FDA 510(k) clearances from total submissions, with all submissions focused on dental devices. The company's regulatory clearance activity spans from 2001 to 2012, establishing a historical record in the dental device sector. No submissions were denied. The company's cleared device portf...

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