

K091020 BLUEPHASE 20IJun 12, 2009
64 days to decisionK091020 · Product code: **EBZ** · Dental
Source: <https://www.510kdatabase.net/k091020/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Activator, Ultraviolet, For Polymerization (EBZ) |
| Date received | Apr 9, 2009 |
| Decision date | Jun 12, 2009 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Ivoclar Vivadent, Inc. |
| Location | Amherst, NY, US |
| Contact | DONNA MARIE HARTNETT |
| Website | https://www.ivoclar.com |
| 510(k) history | 65 submissions · 65 cleared · 2001-2026 |

Ivoclar Vivadent, Inc. is a dental solutions provider based in Amherst, US. The company develops modern products for dental practitioners and laboratory technicians. The company has received FDA 510(k) clearances from total submissions since 2001. Dental devices represent 97% of its regulatory portfolio. The latest clearance was issued in 2026, confirming active market engagement. Recent cleared devices include restorative materials, adhesives, CAD-on restorations, bulk-fill composites, and curing lights. The product portfolio spans chairside and laboratory workflows for ...
