

**K163346 MAZIC Duro**Mar 17, 2017  
108 days to decisionK163346 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k163346/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Material, Tooth Shade, Resin (EBF) |
| Date received         | Nov 29, 2016                       |
| Decision date         | Mar 17, 2017                       |
| Days to decision      | 108 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Vericom Co., Ltd.</b>                |
| Location       | Anyang-Si, Gyeonggi-Do, KR              |
| Contact        | Myung-Hwan Oh                           |
| 510(k) history | 19 submissions · 19 cleared · 2004-2025 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163346/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026