

**K082383 FORTOSS VITAL**Sep 5, 2008  
17 days to decisionK082383 · Product code: **LYC** · Dental  
Source: <https://www.510kdatabase.net/k082383/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Special                                 |
| Device classification | Bone Grafting Material, Synthetic (LYC) |
| Date received         | Aug 19, 2008                            |
| Decision date         | Sep 5, 2008                             |
| Days to decision      | 17 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biocomposites, Ltd.</b>  |
| Location       | Keele, GB   |
| Contact        | MARIE WHALLEY   |
| Website        | <a href="https://www.biocomposites.com">https://www.biocomposites.com</a> |
| 510(k) history | 27 submissions · 27 cleared · 2000-2026                                   |

Biocomposites, Ltd. is an international medical device manufacturer based in Keele, GB. The company engineers and manufactures specialized devices for musculoskeletal infection, trauma, spine, and orthopedic applications. Biocomposites has received FDA 510(k) clearances from total submissions since 2000. The company's portfolio is dominated by Orthopedic devices, which represent 89% of its regulatory submissions. The latest FDA 510(k) clearance was granted in 2026, confirming active regulatory engagement. The company's core product lines include antibiotic-loaded bone cem...

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