

**K243078 HexaPLUS S OneDrill Implant System**Oct 10, 2025  
375 days to decisionK243078 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k243078/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Sep 30, 2024                         |
| Decision date         | Oct 10, 2025                         |
| Days to decision      | 375 days                             |
| Third-party review    | No                                   |
| Combination product   | No                                   |
| PCCP authorized       | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Osseofuse International, Inc.</b>  |
| Location       | Calabasas, CA, US                     |
| Contact        | Priscilla Chung                       |
| 510(k) history | 2 submissions · 2 cleared · 2019-2025 |

**REGULATORY CONSULTANT**

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|-----------------|--------------------------------------|
| Consulting firm | <b>LK Consulting Group USA, Inc.</b> |
| Contact         | Priscilla Chung                      |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243078/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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