

**K243731 HEXIM Implant**Jul 9, 2025  
217 days to decisionK243731 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k243731/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Implant, Endosseous, Root-form (DZE) |
| Date received         | Dec 4, 2024                          |
| Decision date         | Jul 9, 2025                          |
| Days to decision      | 217 days                             |
| Third-party review    | No                                   |
| Combination product   | No                                   |
| PCCP authorized       | No                                   |
| Summary / Statement   | Summary                              |
| Other names           | Samwon General Abutments             |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>P&amp;A USA</b>                    |
| Location       | Annadale, VA, US                      |
| Contact        | Jung Shin                             |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

**REGULATORY CONSULTANT**

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|-----------------|-----------------------------|
| Consulting firm | <b>Rook Quality Systems</b> |
| Contact         | Chandler Thames             |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243731/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026