

**K222738 Point implant system**Apr 13, 2023  
216 days to decisionK222738 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k222738/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 9, 2022
Decision date	Apr 13, 2023
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pointnix Co., Ltd.</b>
Location	Great Neck, NY, US
Contact	Chang Nam Lee
510(k) history	2 submissions · 2 cleared · 2013-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Gms Consulting</b>
Contact	BoKyeong Kim

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

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