

**K251441 Inion CPS 1.5 Baby Bioabsorbable Fixation System**Nov 7, 2025  
182 days to decisionK251441 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k251441/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	May 9, 2025
Decision date	Nov 7, 2025
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System

**APPLICANT**

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Company	<b>Inion OY</b>
Location	Tampere, FI
Contact	Hanne Kankaanpää
510(k) history	14 submissions · 13 cleared · 2005-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251441/> 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 14, 2026