

**K191764 Inion BioRestore**Jul 31, 2019  
30 days to decisionK191764 · Product code: **MQV** · Orthopedic  
Source: <https://www.510kdatabase.net/k191764/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Jul 1, 2019
Decision date	Jul 31, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inion OY</b>
Location	Tampere, FI
Contact	Tiina Tyni
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/k191764/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026