

K251961 SDS Growing RodJan 15, 2026
203 days to decisionK251961 · Product code: **PGM** · Orthopedic
Source: <https://www.510kdatabase.net/k251961/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Growing Rod System (PGM)
Date received	Jun 26, 2025
Decision date	Jan 15, 2026
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	BAAT Medical Products B.V.
Location	Rj Hengelo, NL
Contact	Jasper Springer
510(k) history	5 submissions · 5 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251961/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026